# This Page Is Inserted by IFW Operations and is not a part of the Official Record

### **BEST AVAILABLE IMAGES**

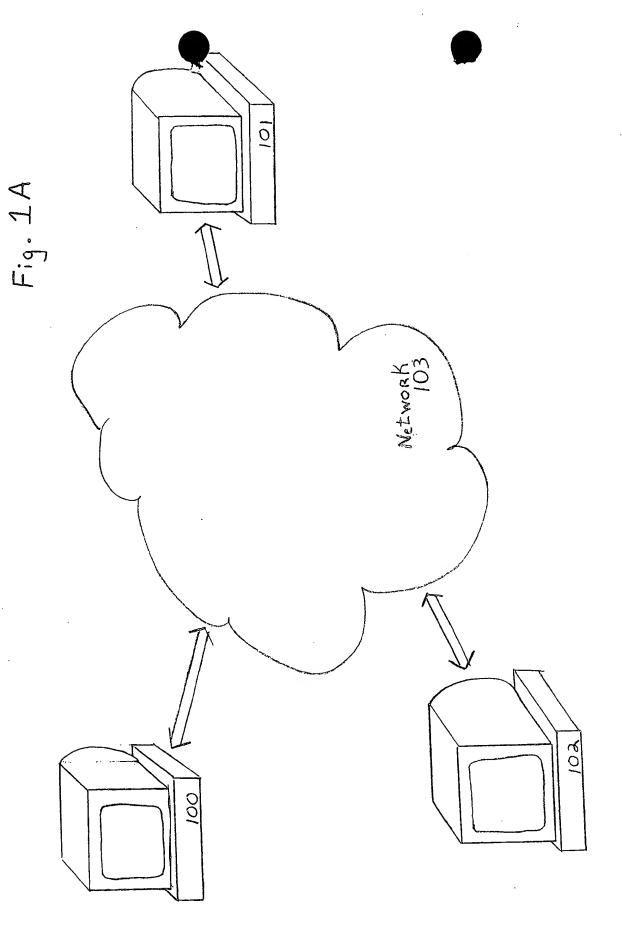
Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

# IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents will not correct images, please do not report the images to the Image Problems Mailbox.



S C C

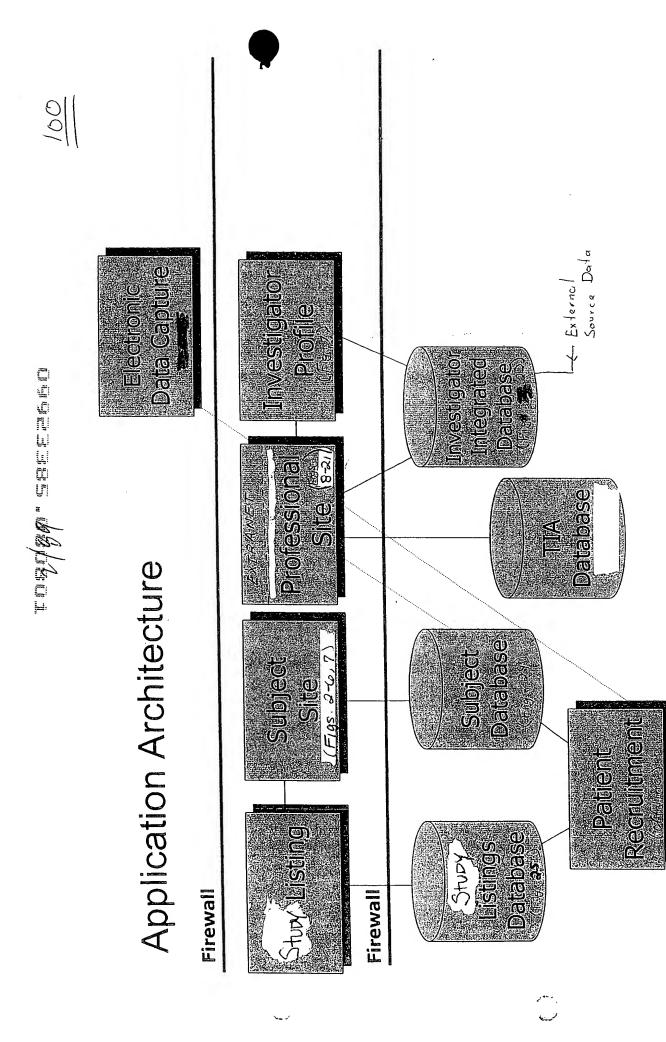


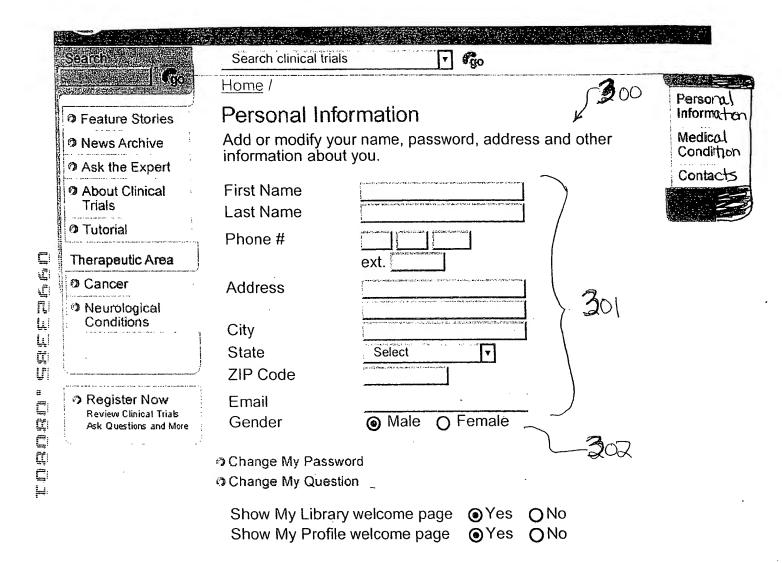
Fig. HD

	Search clinical trials	200
	De wieden u	200
Feature Stories	Register	
· · · · · · · · · · · · · · · · · · ·	To register to become $lpha$ member, just fil	II in the form below.
	Email	and the Mark
About Clinical Trials Tutorial	Username	Username 4-d chars, no blan spaces
Therapeutic Area	Password	Password 4-4
© Cancer Qo3	Retype Password	case-sensitive
Conditions	Your privacy is of the utmost concern to us. For n Privacy & Security Policy. 20나	more information, read
Registen Now Review Clincol Trials Ask Questions and More	As part of the registration process and to protect you please choose one of the questions in the boanswer into the second box. If you forget your pabe given to you. After correctly answering the quereset your password so you can have full access	ox below and type the assword, this question estion, you will be aske
	Your question What is your mother's maiden nar	me? ▼
205	Your answer, up to 45 characters.	
		▼
	Terms of Service	
	Please read the following Terms of Service agree	ement
ZOO	TERMS OF SERVICE AGREEMENT	
		<u> </u>

Fig. 2A

- out how you can be considered for participation in clinical trials
- The ability to ask questions of OUR medical experts
- Timely, relevant announcements of new trials and drug information
- Exclusive interactive tools, including your own personal library of news information
- Emails informing you of updates to our clinical trial listings, news and information, tailored to your selection.
- A personal profile used to optimize your experience.

F16. 23



Save

Fig. 3

earch	Search clinical trials	₹ fgo		
	Home /		( <b>\$</b> 00	Perso
Feature Stories	Medical Conditi	ons	× 4	Inforn
News Archive	Select conditions that			Medic
	information you would			Cond
Ask the Expert     ■	therapeutic area in the "View" to see the cor	ie pulldown menu ai	nd then click	Cont
About Clinical Trials	view to see the cor	iuitions that ian with	iii tiiat aica.	
and the	If you'd like to see ar	nother therapeutic a	rea, simply go to	
7 Tutorial	the pulldown menu, r	make another select	tion and then click	
Therapeutic Area	"View." The page wil	l automatically displ	ay the new	
9 Cancer	therapeutic area.	,	<b>-1</b> 1.0	
was a supple surference of the	40		- BOX	
<ul> <li>Neurological Conditions</li> </ul>	Cancer	View		
Conditions		Technology and Company of the Compan		
	_			
	Cancer		4	
3 Pagister Now	Please email me upo	dated information or	1: A -	
Register Now Review Clinical Trials	·	404	405	
Ask Questions and More	O a sea altiti a se	Medical	Clinical Trial	
and the second s	Condition	News/Drugs	Opportunities	-
	Abdominal Cancer			
	Acute T-Cell Lymphoma		<u></u>	AC
•	Adrenal Cancer	ş		7
	Bladder Cancer	 1	ات. 1 : "ا	•
	Bone Marrow	e de la constante de la consta	<u></u> -	
	Transplant			
	Bone Metastases	(Marin		
	Brain Cancer		Barrettine	
	Breast Cancer		a <sup>rre</sup> ze Ž	
	Cancer Pain	$\overline{\gamma}$	U1 437-9 6 6	
	Cancer/Tumors	<u>-</u>	ក	
	Cervical Cancer	 1		
	Cervical	l ,	ا <del>س</del> ن ه	
	Neoplasia			
	Chemotherapy	ت	**************************************	
	Colon	<u>-</u>		
	Malignancies	_1	اسن	
	Colon Polyps			
	Colorectal Cancer			
	Effects of	1	1	
	Chemotherapy Endometrial	,I		
	Cancer	1	1	

F161.

	^		
--	---	--	--

Sopriagear		
Cancer Chromatic Procest	;""\	,
Fibrocystic Breast Gall Bladder		<del>-</del>
Sancer Sancer		3-5
Gastric Cancer		
Gliomas		Ī
Head and Neck		
Cancer		
Hepatoblastoma	11964	\$0.00
Histiocytoma	<u>"</u>	ũ
Islet Cell Cancer		Lap.
Kaposi's Sarcoma	Ī	
Kidney Cancer		Chair.
Leukemia		
Liver Cancer		
Lung Cancer		y com
Lymphomas		
Malignant		
Adenoma	Ĩ	
Malignant		
Melanoma	<u>'</u> '	<b>.</b>
Medical		
Prosthetics		است پران
Meningiomas	<u> </u>	
Mesothelioma		
Metastatic Cancer		
Multiple Myelomas		- "
Mycosis	Í	£ <sup>™</sup> [
Fungoides	<b></b>	
Neoplasms	<u> </u>	
Neurectoderma		
Neuroblastoma		
Neurofibromatosis		الله الله
Non-Hodgkin's	, m	. Funar
Lymphoma	<del></del>	
Oral Cavity Cancer		<u></u>
Ovarian Cancer	- 1	tur app
Pancreatic Cancer		
		اب است.
Pelvic Cancer	<del></del>	<b>'</b> —
Platelet Deficiencies		
Prostate Cancer	•••	9 <sup>07</sup>
Rectal Cancer	_ 	اسن
Rectal Calicel Renal Cell		ا
Carcinoma		
Sarcoma	ſ	!
Skin Cancer	 	
OKIII Garicoi		

	8/89		
Spinal Cord Malignancy	<u> 1</u>	<u>. ``</u>	
Stomach Cancer		d.	
T-Cell Lymphoma		<u></u>	
Testicular Cance	r 🔏	<u>a</u>	
Thrombocytopen	ia 📋		
Thymomas	great rest	1	
Vaginal Cancer			
Vulvar Carcinom	а 🔲 .		
Wilms' Tumor			

Save

F16. 40

# Clinical

Search clinical trials ▼ Go Home / About Us / **About Clinical Trials** Feature Stories News Archive Search Clinical Trials Ask the Expert Neurological Conditions Cancer About Clinical Obstetrics/Gynecology Trials Cardiology/Vascular Diseases Ophthalmology Dental/Maxillofacial Surgery Tutorial Otolaryngology Dermatology Plastic Surgery 10€ Therapeutic Area Pediatrics/Neonatology Endocrinology Cancer Pharmacology/Toxicology Gastroenterology Pulmonary/Respiratory Diseases Neurological Hematology Conditions Rheumatology Immunology/Infectious Diseases Ш Trauma/Emergency Medicine Musculoskeletal Œ! Nephrology/Urology U Clinical Trials FAQ Register Now Review Clinical Trials Introduction: What are clinical trials? Ask Questions and More 

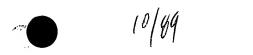
- Why are clinical trials important?
- The clinical trial process.
- How are participant's rights and safety protected during a clinical trial?
- Who pays for clinical trials?
- Where can you get more information about clinical trials?
- Questions you need to ask.
- Common terms used in clinical trials.

#### Introduction: What are clinical trials?

Quite simply, a clinical trial is a very carefully structured study that evaluates the effectiveness of a drug against a specific disease or condition. Clinical trials can focus on a new drug or they may be used to determine new uses for existing medications.

When a promising new medication is identified, the drug undergoes careful evaluation for safety and effectiveness through the clinical trial process. Typically, the doctors chosen to conduct clinical trials are experts within their medical specialties. The pharmaceutical or biotechnology company that is sponsoring the trial reports their findings to the U.S. Food and Drug Administration (FDA). The FDA reviews those findings and if they determine that the drug is both effective and safe to use, then they will make the

FIG.



drug available for broader use by doctors and their patients.

Doctors conducting clinical trials frequently ask their patients if they are interested in volunteering to participate in a clinical trial. Each trial has different requirements for how it is conducted, such as conditions for patient eligibility, length of the study, dosage of the study drug, and types of medical procedures, to name a few. If you are interested in participating in a clinical trial, it is very important that you review these requirements with the doctor conducting the clinical trial to ensure your eligibility and to determine the potential benefits and risks from the trial.

If you are looking for clinical trials that may be beneficial for you, please search our clinical trials listing for details on type and location. This is the first step to review the exciting medical research on the potential new treatments of tomorrow that may benefit you today.

Back to top

#### Why are clinical trials important?

Clinical trials are important to increase medical knowledge and find better ways to help people. Generally, the goal of clinical trials is to introduce an investigational treatment that is safer and more effective than the standard treatment for a particular disease or condition. In addition, for those diseases for which there are no treatment options, research and clinical trials may be the only avenue to uncover a potential treatment.

Back to top

#### The clinical trial process.

After a drug is successfully tested in laboratory and animal studies, the FDA grants approval for testing to begin in humans. The testing of drugs in clinical trials - also called clinical studies or clinical research - usually occurs in three and sometimes four different phases or steps. Each phase normally involves a larger number of people.

Phase I. In Phase I trials, researchers study how quickly an investigational treatment works and how the human body processes the investigational treatment. They also try to find dose ranges that will produce the desired effects. Phase I trials typically involve healthy volunteers, but sometimes severely ill patients will participate in these trials.

Phase II. In these trials, the safety and effectiveness of an investigational treatment is studied in larger groups of people who have the disease or condition to be treated.

F16. \$B



Phase III. In Phase III trials, the safety and effectiveness of an investigational treatment are studied in larger populations of people for whom the drug is intended. Typically, there are hundreds or thousands of people in a Phase III trial. Often, the investigational treatment is compared with standard treatments in hopes of finding better ways to help people. The pharmaceutical or biotechnology company that is sponsoring the trial reports the findings from Phase III trials to the U.S. Food and Drug Administration (FDA).

Phase IV. Phase IV trials are also called post-marketing trials. Only after the FDA has determined that the medicine is both safe to use and equivalent or superior to existing therapies is it then made available for broader use by physicians and their patients. Phase IV trials take place after a drug has been approved. Findings from Phase IV trials provide additional information about the safety and efficacy of the drug.

Back to top

# How are participant's rights and safety protected during a clinical trial?

The FDA is the government agency that develops policies and guidelines that protect the rights, safety, and well-being of people involved in clinical research. The rights and safety of people participating in clinical trials are also protected by an Institutional Review Board and by an informed consent form. An Institutional Review Board (IRB) is comprised of both physicians and lay people for the purpose of studying the design of the trial and ensuring that participant's rights are maintained. The informed consent form explains the clinical trial and outlines a participant's rights. You should always be given an informed consent form prior to enrolling in any clinical trial.

Back to top

#### Who pays for clinical trials?

- Sponsors fund clinical trials. This funding can come from the federal government via the National Institutes of Health (NIH) or directly from pharmaceutical and biotech companies.
- The clinical trial sponsor contracts with specialized physicians and/or researchers to administrate the trial. Settings for the trials could range from the physician's office to a hospital or research facility. Reimbursement for this service is typically paid out on a per-patient basis.
- Sponsors may pay you to participate in a clinical trial.
   Typically, these fees, when provided, are nominal.
- Medical care is often provided at no cost to the



patients, but they still may be responsible for other expenses such as travel between their homes and the healthcare facility.

Patients may also have to pay for some medical procedures, tests, or hospital stays if these are considered a part of standard treatment and not part of the clinical trial. Before you enroll, you should determine exactly who pays for what services.

Back to top

# Where can you get more information about clinical trials?

If you or someone you know has a medical problem and is thinking about taking part in a clinical trial, speak to your healthcare provider first. In taking an active role in the management of your health, you may want to work closely with your provider to find out if a particular clinical trial is right for you.

@ Back to top

#### Questions you need to ask.

- What is the length of your involvement in the clinical trial? How long will the trial last?
- Where will you have to go in order to participate in the clinical trial?
- What are the possible treatments you may receive while in the clinical trial?
- Do the treatment alternatives they provide cover all possible treatments for this disease? If not, what are your other treatment alternatives?
- What procedures are built into the study to keep you safe from harm while you are participating?
- What are the risks and benefits of participating in the clinical trial?
- If there are risks, what will happen should you have an adverse reaction to the treatment in the study?
- What costs may you incur if you participate?
- Will the treatment be available to you even after the clinical trial has concluded?
- Where are the funds coming from to conduct this trial? What is their purpose in sponsoring the trial?

You should also feel free to ask any other question about the trial you want answered.

@ Back to top

#### Common terms used in clinical trials.

Clinical trial: A clinical trial - also called a clinical study or clinical research - is a way to evaluate the safety and

F16 5D

benefits of a new drug in a carefully controlled setting. The new drug is tested in people who volunteer to participate in the trial.

Clinical investigator: A clinical investigator is a doctor or scientist who is responsible for carrying out the planned research activities for a clinical trial. Typically, the doctors chosen for these clinical activities are experts within their medical specialties.

Coordinator: A coordinator is a person (usually a nurse or other medical professional) who is responsible for organizing the planned clinical research activities for a trial. The coordinator is also responsible for taking care of important study documents.

Food and Drug Administration: The Food and Drug Administration is often referred to as the FDA. The FDA is a government agency that develops policies and guidelines that protect the rights, safety, and well-being of people involved in clinical research. The FDA also enforces the laws that govern the approval, regulation and monitoring of drugs and medical devices.

**Informed consent:** Informed consent is a process that confirms a patient understands the nature of the study, the risks involved, and the expected benefits of treatment. A written and dated form called the "informed consent form" is signed by a patient to document this process.

Institutional Review Board: An Institutional Review Board is usually referred to as the "IRB." The IRB is a group of medical, scientific, and nonscientific people that are responsible for reviewing and approving the planned clinical activities of a study. The group ensures the protection of the rights, safety, and well-being of patients who volunteer for clinical trials.

Investigational treatment: Investigational treatment is another term for the drug, treatment, or medical device that is studied in a clinical trial.

**Principal investigator:** The principal investigator is the doctor or researcher who is put in charge of all clinical activities at a particular study location and who supervises the care of patients in the study.

**Protocol:** A protocol is a plan that contains guidelines for a clinical study. The pharmaceutical or biotechnology company that discovered the investigational treatment usually develops the protocol.

**Sponsor:** The sponsor is the organization that funds a clinical trial and that develops a plan for the research. The organizations can be a pharmaceutical or biotech company, a research institution, or other health organization.

Amont in a torm

Standard treatment: Standard treatment is a term that refers to approved medical procedures, drugs, tests, or hospitalizations that are a part of the general care considered to be appropriate for certain diseases and conditions. It is the 'best treatment' currently known for a given disease. If there are no current treatments shown to be effective against a particular disease, then no treatment would be the standard treatment for that condition.

Back to top

F.G. 5F

•	
Search	Search clinical trials
(02)	Home / Cancer /
© Feature Stories	Clinical Trials
News Archive	Search Clinical Trials
<ul><li>Ask the Expert</li><li>About Clinical</li></ul>	Use these search criteria to find clinical trials.
Trials	Select a condition
7 Tutorial	and/or
Therapeutic Area  Cancer	Select a state v cgo 503
Neurological Conditions	
· Conditions	⊕ Contact me for a clinical trial 60 4
<u> </u>	Welcome to Clinical Trials
© Register Now Review Clinical Trials Ask Questions and More	When a promising new medication is identified, of evaluation of the safety and effectiveness of the occurs in the clinical trials process. Typically, the chosen to conduct clinical trials are experts with medical specialties. Findings from the clinical trials

When a promising new medication is identified, careful evaluation of the safety and effectiveness of the drug then occurs in the clinical trials process. Typically, the doctors chosen to conduct clinical trials are experts within their medical specialties. Findings from the clinical trials are reported by the pharmaceutical or biotechnology company that is sponsoring the clinical trial to the US Food and Drug Administration — the FDA. Only after the FDA has determined from reviewing the findings from clinical trials that the medicine is both safe to use and effective is it then made available for broader use by doctors and their patients.

Doctors conducting clinical trials frequently ask their patients if they are interested in volunteering to participate in a clinical trial. Each trial has different requirements for how it is conducted, such as conditions for patient eligibility, length of the study, dosage of the study drug, and types of medical procedures, to name a few. If you are interested in participating in a clinical trial, it is very important that you review these requirements with the doctor conducting the clinical trial to ensure your eligibility and to determine the potential benefits and risks from the trial.

If you are looking for information on where clinical trials are taking place and the types of trials that are available, you can search our clinical trials listing. If you want to learn more about clinical trials, please see our About Clinical Trials page. These are the first steps in learning about clinical trials and in deciding how medical research on

FIG- 64

clinical trials and in deciding how medical research on possible treatments for tomorrow may help you today.

About Clinical Trials will provide you with more information.

F161.6B

F16,60

	home i register i login my library, i my profile (i about us) i help.	
Search	Search clinical trials 💆 🔞	XX
Go	Register Step 1 of 3	
9 Feature Articles		
Medical News	Welcome!  To register with we invite you to complete the following questionnaire	
Ask the Expert	about you and your health. This should take approximately 5 minutes to	8
All About     Clinical Trials	complete. will use the information to present you with new medical therapy and clinical trial information that is of specific interest to you.	
<b>9</b> Tutorial		
Therapeutic Area	Your privacy and security are very important to us; therefore we encourage you to review our <a href="Privacy &amp; Security Policy">Privacy &amp; Security Policy</a> .	
@ Cancer		
Neurological Conditions	Choose Your Username and Password	
L.	Please choose a username	
	Please choose a password	
Ø Register Now  ■ Review Clinical Trials	Please re-type your password	
Ask Questions and More	Choose your reminder question What is your mother's maiden name	
	Please enter your answer to the question	
4!   <b>-</b>     <b>-</b>	Are you seeking information for yourself, or for someone else?	
•		8
	C I am seeking information for someone else	
		7. 7.
	Continue	
		8
	; cw	ith 🖔
		没压

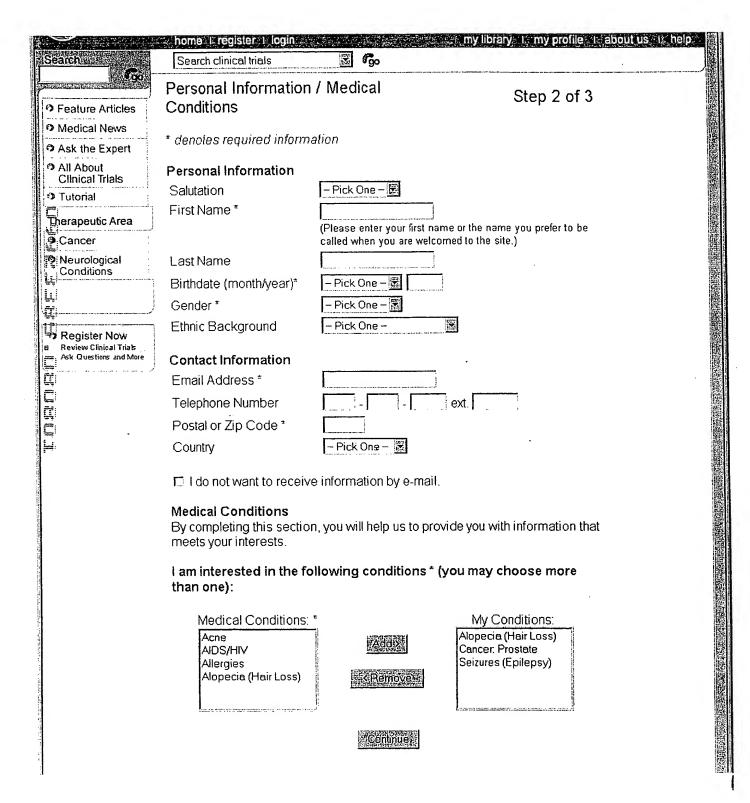
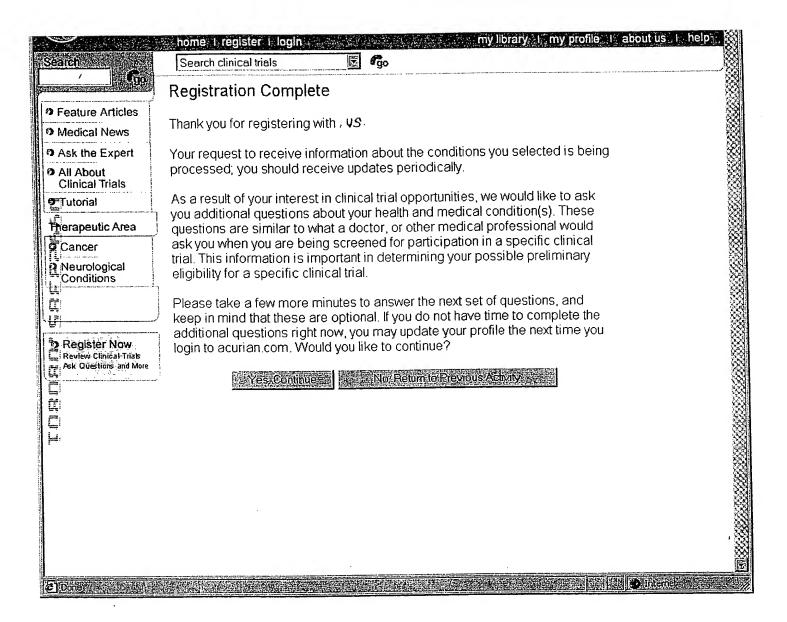


Fig. GE

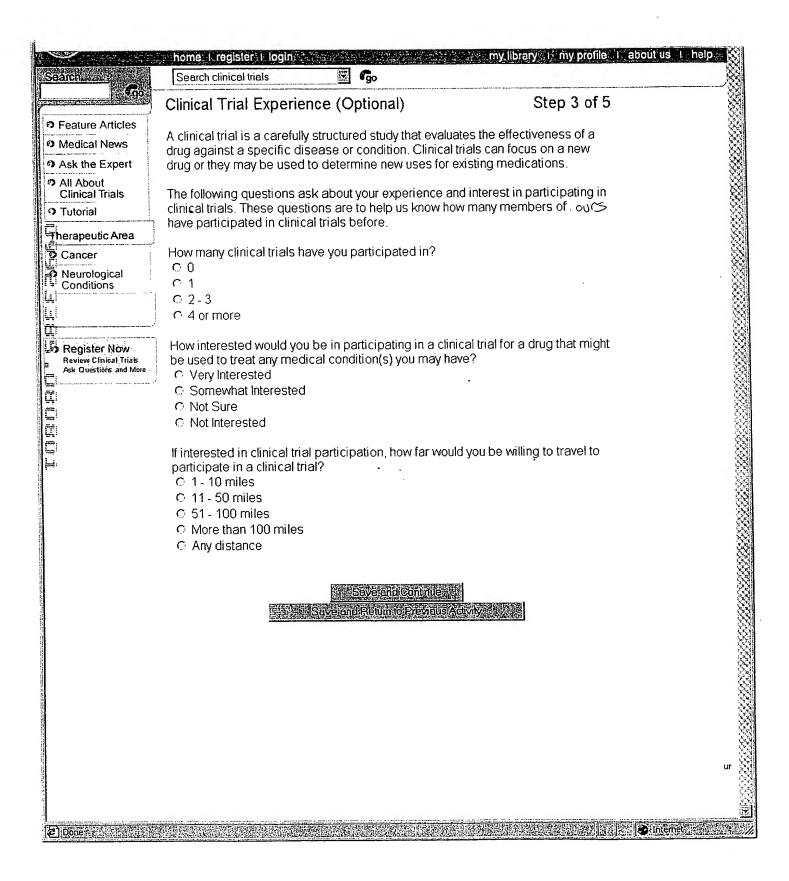
Æί

	, home / register ∣ login my librar	y. I. my profile   about us   help
Search	Search clinical trials	
Coo	Information Request	Step 3 of 3
Feature Articles     Medical News	I would like to receive information about my conditions:	
Ask the Expert		
O All About Clinical Trials  O Tutorial	Alopecia (Hair Loss): ☐ Send me Clinical Trial Opportunities ☐ Send me News and New Medical Therapies ☐ Do not send me information	
Therapeutic Area  © Cancer		
Neurological Conditions	Cancer - Prostate: ☐ Send me Clinical Trial Opportunities ☐ Send me News and New Medical Therapies ☐ Do not send me information	
Pagister Now Review Clinical Trials Ask Questions and More	Seizures (Epilepsy): ☐ Send me Clinical Trial Opportunities ☐ Send me News and New Medical Therapies ☐ Do not send me information	-
후: - -	Terms and Conditions	
	Please read the following Terms and Conditions Agreement  TERMS AND  CONTITIONS	(65T)
	By selecting "I Accept", you are accepting the Terms and Co and will become a registered user.	onditions above

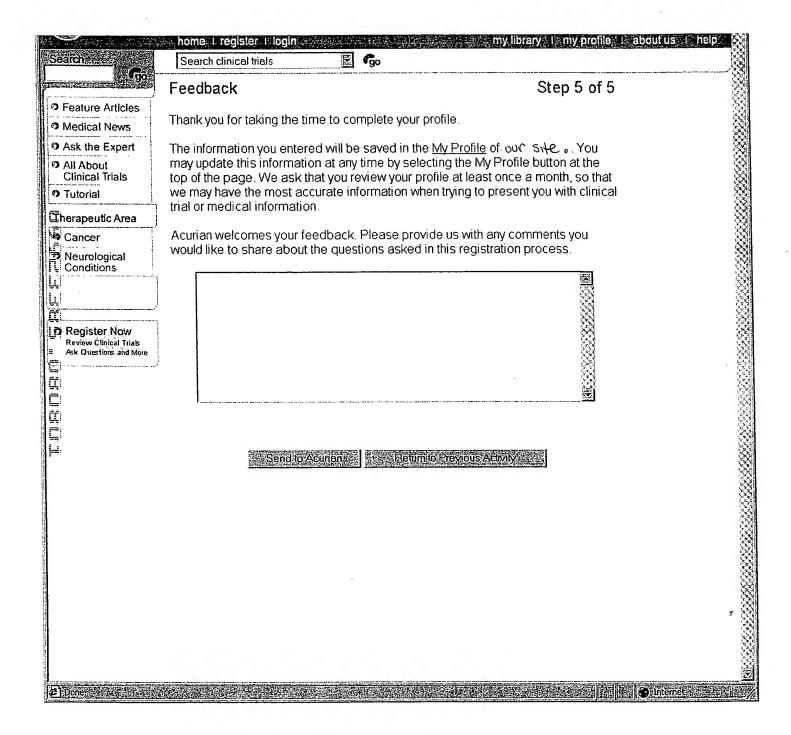


	🧀 home i register i login		Secret in	y library∞ (∶my profile : 1. about ι	ıs I help 🥻 🦠
Search	Search clinical trials	<b>₽ 6</b> 90			
L co	Medications (Optional)			Step 1 of 5	<b>\$</b>
Peature Articles		2.3	(OTO)		33
Medical News	Are you taking prescription (F conditions?	xx) or over-tne-col	inter (OTC) me	edications for these	\$8
Ask the Expert	conditions.				8
All About Clinical Trials	Your Medical Conditions	Prescription	Over-the- Counter	No Medications	
● Tutorial	Alopecia (Hair Loss)				
Therapeutic Area	Cancer: Prostate	II.	$\Box$	ū	Š
Cancer	Seizures (Epilepsy)				
Neurological Conditions					
	Do you take medications for	any of the following	a conditions:		
	Do you take me areasone in	any event rement	9		
Register Now	Medication	Yes		No	Š
Review Clinical Trials  Ask Questions and More	Allergies or Asthma	Ö		C	
i	Heartburn	C		<b>O</b>	
Q.	Diabetes	င		O	Š
	High Blood Pressure	C		C	
다.	Pain	0		C	<b>\{\}</b>
	Thyroid Disorders	O		O	8
	Heart Conditions	C		C	Ž.
					Š
		Severand Cont	nue		Ž.
		e and Relumio Pre	and the comment of th		X
	Seas (100) To the season (100)	en e	ericani i internationali in manageri i	The state of the s	<u> </u>
					× ×
					Š
					Š
				•	* ************************************
					, Š
NAME OF STREET	Control of the Contro	entropolitical content and the content of the conte	Saurahan Wangaran Sebagai and Apida med	NORTH MANY CONTROL OF CONTROL OF THE	
2)Done N					met of talks

	home   register   login   my prome   au	out us. T. Help
Searcha	Search clinical trials 😨 🚱	
<b>G</b> o	Health Habits (Optional) Step 2 of 5	
P Feature Articles		
Medical News	It is often important to know your health habits when presenting you with possible	
Ask the Expert	clinical trial opportunities	
2 All About	How often do you exercise?	
Clinical Trials	O Never	20 20
Tutorial	C Once a week	
Therapeutic Area	C Twice a week	
Cancer	C Three times a week	
	C Four or more times a week	
Neurological Conditions	© Daily	
	How often do you visit your primary care physician?	
<b>[</b> 4	Once a year	2.23
O Register Now	7 2-4 times a year	
Review Clinical Trials	© Every month © I do not have a primary care physician	
Ask Questions and More	J 100 HOL have a primary care physician	
	Do you smoke cigarettes?	5
	C No, I have never smoked	6.5
	○ No, I quit smoking	
	© Yes, daily	
	If you smoke, how many cigarettes do you smoke per day?	
	Please enter: Cigarettes Per Day	
	If you smoke, how old were you when you started smoking?	
	Please enter: years old	
	Do you drink alcoholic beverages?	
	O No	ii, cimmente
	○ Yes, occasionally	
	C Yes, 1-2 drinks per day	
	© Yes, more than 2 drinks per day	
	Overall, how would you rate your health?	
4-12	© Excellent	
	C Good	
	C Fair	
	C Poor	
	Save and Continue 12	
	Saverand Return to Previous Activity	
1	Section of the Control of the Contro	
(a) Done		internet - Frequency



Search clinical trials  Feature Articles  Medical News Ask the Expert All About Clinical Trials  Therapeutic Area  Register Now Register Now Review Chiefial Taba Ask Ousetiers and Mores  Cancer Prostate Accountions  Register Now Review Chiefial Taba Ask Ousetiers and Mores  Cancer Prostate Accountions  Cancer Prostate Accountions  Register Now Review Chiefial Taba Ask Ousetiers and Mores  Cancer Prostate  Cancer Prostate  Cancer Alopecia (Hair Loss)  Cancer Condition  Condition  Complete  Alopecia (Hair Loss)  Cancer Prostate		nome, I register. I login	ः my libraryः। my profileः।। about t	is: i: help :
OF Feature Articles  OF Featu		Search clinical trials		
P Medical News  P Ask the Expert  All About Clinical Trials  Therapeutic Area  Cancer  Neurological Conditions  Register Now  R	<b>90</b>	Clinical Trial Questions	Step 4 of 5	
opportunities. When you are screened for a clinical trial, the doctor at the trial site needs to know more information about your health and the medical condition(s) for which you have been diagnosed. Your answers to the following questions may help determine if you may potentially qualify for a specific clinical trial.  Therapeutic Area  Therapeutic Area  Cancer  Neurological Conditions  Review Chileal Trials  Ak Questionnaire  Condition  Review Chileal Trials  Ak Questionnaire  Cancer. Prostate  Seizures (Epilepsy)  Seevant Communication a check on a chinical trial, the doctor at the trial site needs to know more information about your health and the medical condition(s) for which you have been diagnosed. Your answers to the following questions may help determine if you may potentially qualify for a specific clinical trial.  Listed below are the conditions, ou check mark will appear to the right.  Your information about your health and the medical condition(s) for which you have been diagnosed. Your answers to the following questions may help determine if you may potentially qualify for a specific clinical trial.  Listed below are the conditions, ou check mark will appear to the right.  Your information about your health and the medical condition(s) for which you health and the medical conditions or the following questions may help determine if you may potentially qualify for a specific clinical trial.  Listed below are the conditions, ou check mark will appear to the right.  Your information will be saved after you complete each section. If you are unable to complete these at this time, we will ask you to update your profile the next time you login to acurian.com.	Feature Articles			
Ask the Expert All About Clinical Trials Cancer Conditions Register Now Review Cinical Trials Register Now Review Cinical	Medical News	express opportunities. When you are screened for a clir	ed Interest in clinical trial nical trial, the doctor at the trial site	
Clinical Trials  Therapeutic Area Therapeutic Area Cancer Neurological Conditions  Register Now Review Clinical Trials Ak Guestions and More  Seizures (Epilepsy)  help determine if you may potentially qualify for a specific clinical trial.  Listed below are the conditions you selected earlier in the questionnaire. After you answer questions about each condition, a check mark will appear to the right. Your information will be saved after you complete each section. If you are unable to complete these at this time, we will ask you to update your profile the next time you login to acurian.com.  Questionnaire Condition Complete  Alopecia (Hair Loss)  Cancer: Prostate Seizures (Epilepsy)	Ask the Expert	needs to know more information about your hea	alth and the medical condition(s)	Š
Therapeutic Area Therapeutic Area Cancer Neurological Conditions Conditions  Register Now Register Now Register Now Resident Clinical Trials Ack Questions and More Resident Clinical Trials Servenus Clinical Trials Cancer Prostate Seizures (Epilepsy)  Listed below are the conditions you selected earlier in the questionnaire. After you answer questions about each condition, a check mark will appear to the right. Your information will be saved after you complete each section. If you are unable to complete those at this time, we will ask you to update your profile the next time you login to acurian.com.  Questionnaire Condition Complete  Alopecia (Hair Loss) Cancer. Prostate Seizures (Epilepsy)  Save and Continue		for which you have been diagnosed. Your answ	vers to the following questions may  a specific clinical trial	
Therapeutic Area  answer questions about each condition, a check mark will appear to the right. Your information will be saved after you complete each section. If you are unable to complete these at this time, we will ask you to update your profile the next time you login to acurian.com.  Questionnaire  Condition  Register Now  Review Cinical Trials Ask Questions and More  Alopecia (Hair Loss)  Cancer: Prostate  Seizures (Epilepsy)		•		8
Cancer Neurological Conditions  Neurological Conditions  Questionnaire Condition  Register Now Review Cinical Trials Ask Questions and More Seizures (Epillepsy)  Your information will be saved after you complete each section. If you are unable to complete these at this time, we will ask you to update your profile the next time you login to acurian.com.  Questionnaire Complete  Alopecia (Hair Loss)  Cancer. Prostate  Seizures (Epillepsy)	Therapeutic Area			
Questionnaire Conditions  Questionnaire Condition  Complete  Alopecia (Hair Loss)  Cancer. Prostate Seizures (Epilepsy)  Save and Conditions  Save and Conditions  Save and Conditions  Conditions  Complete  Alopecia (Hair Loss)  Cancer. Prostate  Seizures (Epilepsy)	4 <u></u>	Your information will be saved after you complete	ete each section. If you are unable	
Questionnaire Condition Complete Alopecia (Hair Loss) Review Cinical Trials Ask Questions and More Seizures (Epilepsy)  Save and Continue		to complete these at this time, we will ask you t	to update your profile the next time	
Condition Complete Alopecia (Hair Loss) Review Cinical Trials Ask Questions and More Seizures (Epilepsy)  Save and Continue	Conditions	you login to acunanteom.		
Register Now Alopecia (Hair Loss) Review Cinical Trials Ask Questions and More Seizures (Epilepsy)  Seizures (Epilepsy)	Ļ		=	
Review Cinical Trials Ask Questions and More  Seizures (Epilepsy)  Seizures (Epilepsy)  Save and Continue			·	
Seizures (Epilepsy)	Review Clinical Trials			
	Ask Questions and More			
	<u> </u>	Seizures (Epilepsy)	l_i	No.
	u. Ci			Ş
AND CONTRACTOR AND CO			•	
Save and Return to Previous Activity.		100 C	South and the second se	Š
ı		Save and Return to Pre-	acus Activity - St	E .
ır				
·				
ı				
·ar				8
·ır				8
·ur				
ı				ar S
				ڎۣ



	home i register. I login my library i my profile it about us i help
Seatch	Search clinical trials
	Thank You
Peature Articles Medical News Ask the Expert All About Clinical Trials Therapeutic Area Cancer Neurological Conditions Register Now Review Clinical Trials Ask Questions and More	



- Ask the Expert
- About Clinical Trials
- 7 Tutorial

#### Therapeutic Area

- Cancer
- Neurological Conditions
- Register Now Review Clinical Trials Ask Questions and More

Search clinical trials

#### Home / Knowledge Center /

# Welcome to My Library

Here's your chance to create a library of your very own. My Library is where you can store all kinds of information found throughout the site. Whether it's clinical trial information, abstracts on news articles, drug information. perspectives from our medical experts or personal stories, links to the items you select will be saved in this area for as long as you choose to keep them there. All you have to do is click the "Save to My Library" button found throughout the site.

TO

In addition, you can type in personal notes along with the items you save. We will not access, use, or review your personal notes for any reason.

If you'd like to go directly to one of the five sections, select a link below:

- News
- Drug Information
- O Clinical Trials
- Ask The Expert
- Feature Stories
- Do not show this page again.



participated in trials? \*

FIG 7A

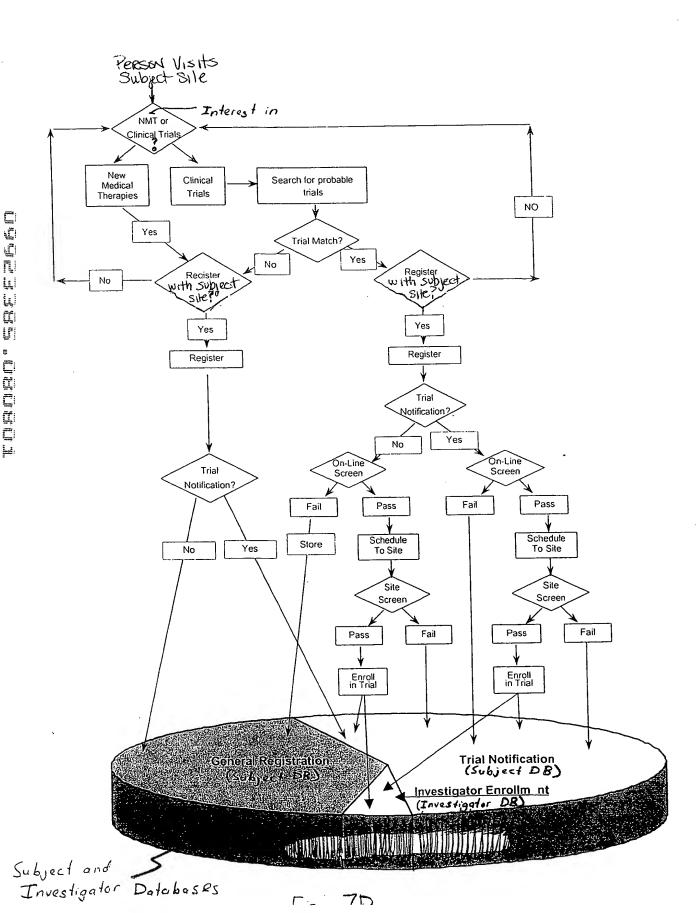
30/	189	
Indicate all phases of clinical research in which the Investigator participated *	☐ Phase II ☐ Phase II ☐ Phase IV	706
How many investigators [conduct research at this PRF? *	investigators	107
Is the Investigator affiliated with: (check all that apply)	☐ Local IRB ☐ Central IRB☐ IEC (Canadian sites only)	
If affiliated with a local IRB, what is its name?		
How often does the local IRB meet?	☐ Weekly ☐ Bi-weekly ☐ Monthly ☐ As Needed ☐ Other	708
If "other", frequency of local IRB meeting?		
How soon after the IRB meeting will you receive an approval letter?		
Has the Investigator ever been audited by the Food & Drug Administration (FDA) or any other regulatory agency?	O Yes O No	
1. If yes, what was the date of the audit?		
Who was the auditor?		~\n\ <b>0</b>
If audited, was a 483 issued?	O Yes O No	
What were the results on the audit?	f	
2. If yes, what was the date of the audit?		
Who was the auditor?		
If audited, was a 483 issued?	O Yes O No	
What were the results of the audit?	of	

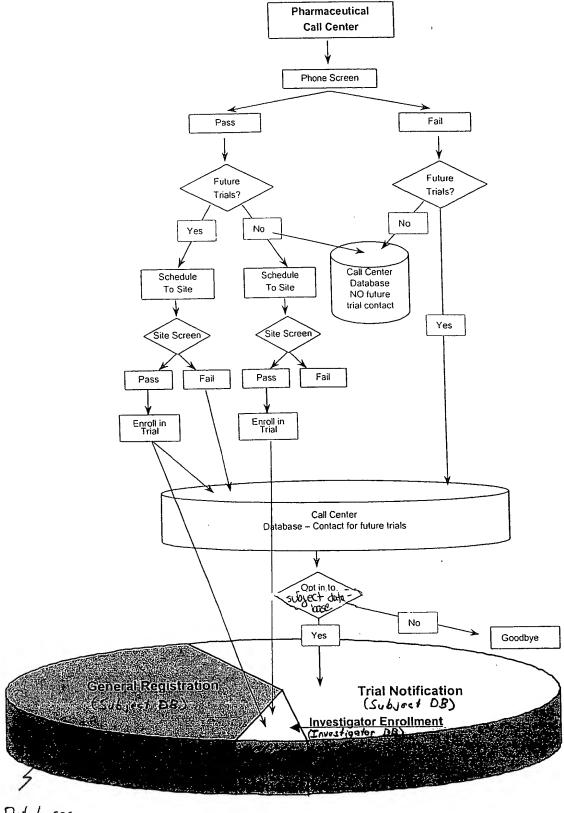
FIG. 7B

3//6	39	
Has the Investigator gone through an audit by a sponsor or CRO?	O Yes O No	
1. If yes, what was the date of the audit?		
Who was the auditor?		710
What were the results of the audit?		
2. If yes, what was the date of the audit?		
Who was the auditor?		
What were the results of the audit?		
-		
Is your PRF	☐ Single specialty ☐ Multi-specialty	
If PRF is multi-specialty, indicate specialties. (one per line)		
Is your facility part of	☐ Solo practice ☐ Group practice	
Is the facility affiliated with a Site Management Organization (SMO) or research group? If affiliated, please specify the SMO name If affiliated, is this an exclusive relationship?	O Yes O No O Yes O No	
(f) Canaal	(A Sawa and Contin	(110

. | | . | . | . | . | . |

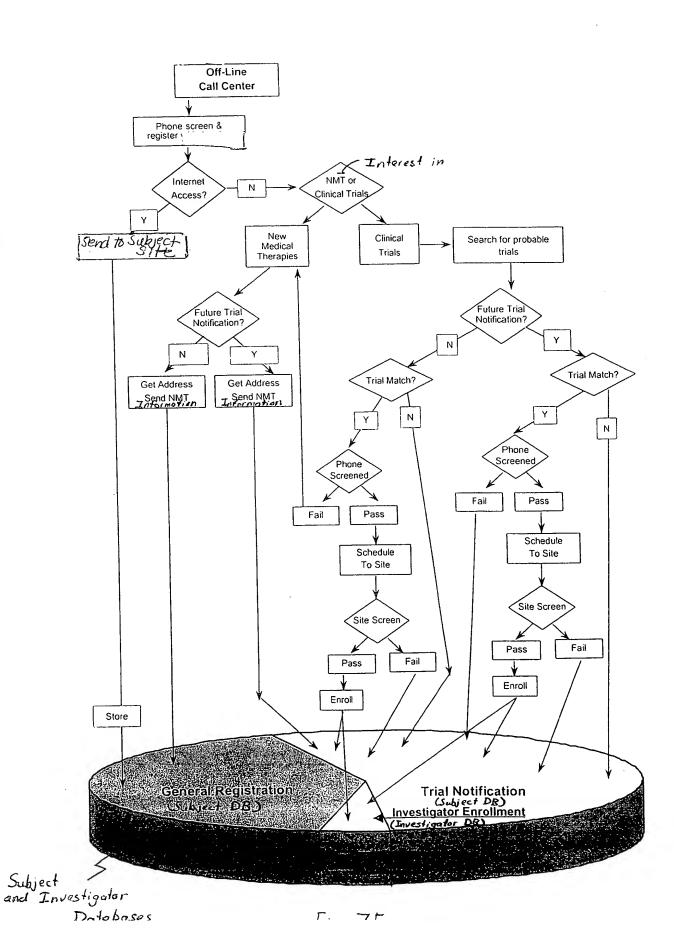
F16,7C

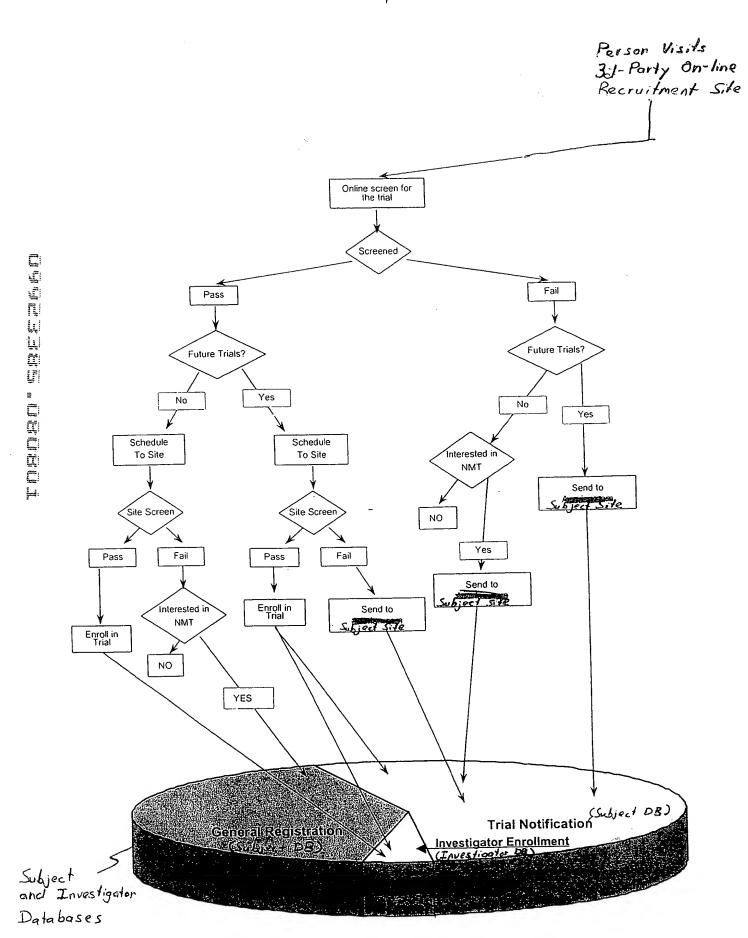


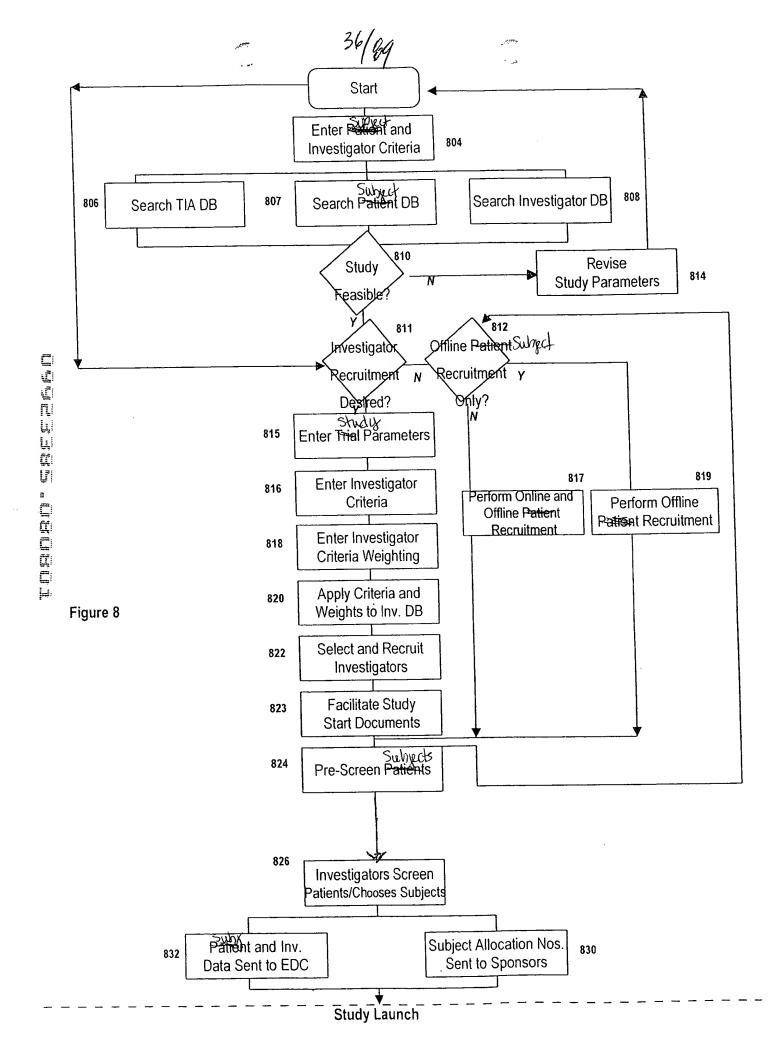


Subject and Investigator Databases

Fig. 7E









	:register	contact ue help
Welcome	<u>Homė</u>	› / <u>Active Trials</u> / Create Trial Parameters
		Create Trial Parameters
		Active Trials files for a specific protocol please t (from a drop down box) information to create ers.

and a such a Challest and Contributes Amount and so.	criai parameters	•
• Register		All fields required
) Services	<b>Protocol Number</b>	
	Protocol Title	<ul><li>□</li><li>□</li><li>□</li><li>□</li></ul>
	Therapeutic Area	Select a Therapeutic Area
	Disease Indication	Select an Indication
	Projected Number of Sites	
	Projected Number of Patients per Site	
	Projected Trial Start Date	January ▼ 2000 ▼ (Month/Year)
	Projected Trial Stop Date	January ▼ 2000 ▼ (Month/Year)
	Projected Enrollment Period (in months)	
	Trial Phase	Select Trial Phase 🔻
	(	Save Trial Save & Search for Investigators

E

Step 1:

To identify potential investigators - please select a specialty.

Nate: To select more than one specialty, point to the specialty and press control click. Limit of 2 selections.

Adolescent Medicine
Aerospace Medicine
Allergy & Immunology

Step 2:

To include the prescribing behavior data in the investigator search results class relevant to the therapeutic area and indication.

Nate: To belect mare than one drug class, point to the specialty and press control click. Limit of 2 belections. Acne Therapy
Aids Therapies
All Other Misc. Ethical Drugs

Step 3:

To include the number of trials conducted by the investigator in the search a number.

1 🕏

Step 4:

Patient Therapeutic Area

Patient Disease Indication

Patient Disease Indication Encounter Category

Nate: To belect more than one patient deceme indication encounter category, point to the specialty and press control click. Limit of 2 polections.

-Select a Category-

Case Load Estimates - Malignancy of heptobiliary system of pancreas Inpatient Discharge Diagnosis - Malignant neoplasm of pancreas

Patient Distance from Site (in miles)

**<=** 3 ₹

Step 5:

To limit search by geographical location- please enter your selections belo

Municipal Area

-Select a Municipal Area - 🥳

Waller Comments Home .

) Rogister

) Active Trials Sucurity & Privacy Policy

Create Trial

FAC

) Services

Displaying 1-20 out of 682 results

/ <u>active Trials</u> / <u>Trial At A Glance</u> / Search

# Investigator Search Results

Hemselv C

The following investigator search results reflect the investigator search cinteria and the patient demographic data selected in the investigator Search. Review selections by scrolling down this page or by clicking here: <u>Investigator.Search.Criteria.Summary</u>. Click a column heading to sort by that column.

Search Results:

4	<b>評</b>
ž\$	
7	
30	450
1	
4	
221	
1	
u,	
3.3	
4	
P.	
2	Co.
7.0	Control of the Contro
ō.	
0	<b>是一个人的</b>
-	10 miles
$\pm$	
	2
10	
2.4	
12.0	
3	<b>经国际企业的</b>
0	
1	1.5
	15
246	
1	
134	part of the same o
1	
100	
1	10.20 Marie 10.00
11.15	
1	
.0	
o	
<u> </u>	
5.	
7.5	(0)
_	20.
1	1
>	
. Н.	
_	

en coerceens.

Handler J  Tibbo C  Schelker J  Tibbo C  Rownsen C  Row	Nen
Cardiovascular Disease Continuouscular Disease Continuouscular Disease Cardiovascular Disease	Specially
	C C
LA JOLLA, CA SALTUREE, WI CONCINNATION CONCINNATION MILWAUKEE, WI CONCINNATION MILWAUKEE, WI MILWAUKEE, WI MILWAUKEE, WI MILWAUKEE, WA MILWAUKEE, PA MILWAUKEE, WA MILWAUKEE, PA MILWAUKEE, WI MILWAUKEE, PA MILWAUKEE, WI MILWAUK	CITY Store
28 4-Average Lengt 27 5-Average Lengt 27 9-Average Lengt 25 36-Average Lengt 26 10-Average Lengt 27 27-Average Lengt 28 4-Average Lengt 19 2-Average Lengt 19 2-Average Lengt 19 3-Average Lengt 19 3-Average Lengt 11 4-Average Lengt 11 3-Average Lengt 12 4-Average Lengt 13 3-Average Lengt 13 3-Average Lengt 14 30-Average Lengt 15 4-Average Lengt 16 4-Average Lengt 17 4-Average Lengt 18 4-Average Lengt 19 4-Average Lengt	33 BE Avairage
28 4-Average Length of Stay - Angin 25 564 Warage Length of Stay - Angin 27 9-Average Length of Stay - Angin 28 10-Average Length of Stay - Angin 28 10-Average Length of Stay - Angin 29 11-Average Length of Stay - Angin 20 11-Average Length of Stay - Angin 21 11-Average Length of Stay - Angin 22 11-Average Length of Stay - Angin 23 11-Average Length of Stay - Angin 24 11-Average Length of Stay - Angin 25 11-Average Length of Stay - Angin 26 11-Average Length of Stay - Angin 27 11-Average Length of Stay - Angin 28 11-Average Length of Stay - Angin 29 11-Average Length of Stay - Angin 20 11-Average Length of Stay - Angin 21 11-Average Length of Stay - Angin 22 11-Average Length of Stay - Angin	
Angin	
1-Anticoagula 1-Anticoagula 1-Anticoagula 4-Anticoagula 1-Anticoagula	J. Anne co apulla
-00-42572745289898989	

Next 20 >

1

1

) Services

) FAQ

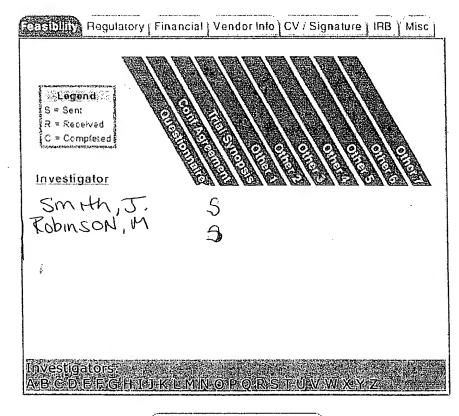
- A Document Summary
- Document View
- > Investigator View

### contact us la help

Home , \_\_\_\_\_ / Active Trials / Trial at a Glance / Document Tracking

# A multi-center study... Document Summary

Summary of document status for the selected protocol. Click on any document to go to Document View by Investigator. Click on any investigator to go to specific Investigator Document View. Study launch documents have been grouped into categories denoted by the tabs below. Click on a tab to view status of documents in that category.



Return to Trial at a Glance

F16, 12

Welcome Home / Tracking

介 Register

345678

) Services

FAQ

> Document Summary

o Document View

> Investigator View

contact us 1 holp

Home / Active Trials / Trial at a Glance / Document Tracking / Document View by Investigator

# **Document View by Investigator**

Summary of document status by investigator. Click on any investigator to go to document history of the document selected in the drop down box. Study launch documents have been grouped into categories denoted by the tabs below. Click on a tab to view status of documents in that category.

Feesibility   Regul	cial   Vendor Info   ( aine	Part of the same o	IRB Misc
Investigator 5 Mith	 Date Sent リ2フトリ	Date Rec'd 1)27 01	Date Completed 1)28101
Investigators: A.B.@D.E.F.G	MNOPORST	Ú V W X Y Z	

From: Service Provider

Sent: June 6, 2000

To: Ms. Moore

Subject: Clinical Trial Opportunity

Dear Ms. Moore:

You may qualify for an upcoming clinical trial opportunity. For additional information go to https://www.website.com/study/zz-234567-22\* and complete the study specific questionaire.

Contact Service. Com with any questions or comments you may have.

Sincerely,

Service Provider

If you have received this message in error or no longer would like to be considered or contacted about clinical trials please go to http://www.servel.com/remove

Ц.

Questionnaire - Alzheimer's

In order to evaluate whether you may be eligible for this study, we will need to review some of your medical history. Are you legally able to provide us with this information for the potential study participant?

Yes, I am the potential study participant

Yes, I am a caregiver for the potential study participant with the ability to provide the potential participant's information for the purpose of seeking enrollment in clinical studies No, I am not legally able to provide this information.

In answering the following questions, "you" or "your" refers at all times to the potential study participant.

Please provide your gender.

- o Male
- o Female

How did you hear about this study?

- o Internet
- o Newspaper Ad
- o Newspaper Article
- o Radio Ad
- o Radio Public Service Announcement
- o TV Ad
- o TV program
- o Physician
- o Friend
- o Support Group
- o Patient Ed Materials
- o Cardiology Newsletter
- Other, please specify:

The purpose of this medical research study is to evaluate the effect of an investigational drug on the ability to reason, remember, imagine, and learn in humans who have already been diagnosed with mild to moderate probable Alzheimer's Disease. You must live with a caregiver or receive daily visits from a responsible caregiver. The caregiver must be familiar with the your recent medical history and be willing to come to 7 doctor visits for a period of 6 months.

After these questions are answered we may be able to refer you to a research site for further screening. After the site reviews your responses to the screening questions, a nurse or other person at the research facility will be calling you. At that time, it will be determined if a first visit should be scheduled to determine whether this study is appropriate for you.

Have you been diagnosed with Alzheimer's disease?

- o Yes
- o No

Have you experienced a deterioration in memory over at least the last 6 months?

IG 15A

- o Yes
- o No

Click the box next to the following if you have experienced a decline in any of the following in at least the last 6 months:

- o orientation
- o judgement
- o problem solving
- o functioning in community affairs
- o functioning in home or hobbies
- functioning in personal care

Do you live in a residential home?

- o Yes
- o No

Click the box next to the person who will serve in the role of Caregiver:

I am the Caregiver

Friend

Relative

Paid personnel

No Caregiver

Please enter your date of birth: 1.

Day

Month

Year (pull-down boxes)

- ☐ If female, continue with question 2
- ☐ If male, continue with question 6
- 2. Are you / Is (Patient) surgically sterile or post-menopausal for 1 year or more?
  - Yes continue with question #6 No – continue with question #3
- Do you / Does (Patient) have any other neurological conditions such as: 3.
  - o Parkinson's disease
  - o Pick's disease
  - o Huntingtons chorea
  - o Down's syndrome
  - o Creutzfeldt-Jacob disease
  - o Other
- Do you now or did you at any time, have one or more of the following conditions 4. resulting in your memory or cognitive impairment:

F16. 15B

- o Major head injury
- o Injury caused by trauma such as boxing
- Vitamin deficiency
  - Type [drop down menu]
- o Brain abscess
- o Syphilis
- o Meningitis
- o AIDS
- Brain cancer
- o Thyroid, parathyroid, or pituitary disease
- o Cushing's syndrome
- Kidney failure
- Uncontrolled diabetes
- o Mental retardation
- 5. Do you have a history of any of the following:
  - o Stroke within the past 12 months
  - o Epilepsy or convulsions (Childhood convulsions caused by fever continue)
  - o Major depression
  - o Stomach ulcer that is currently being treated
  - o Liver, kidney, or lung disease
  - o Kidney stones
- 6. Have you had a heart attack or coronary artery bypass graft surgery within the past 6 months?
  - o No
  - o Yes
- 7. Do you experience angina (chest pain) that required a change in medication in the past 3 months?
  - o Yes
  - o No
- 8. Has a doctor told you that you have a heart rate that is slow or less than 50 beats per minute?
  - o Yes
  - o No
- 9. Do you take medication for high blood pressure or chronic low blood pressure?
  - o Yes
    - o Medication(s) taken: [drop down menu]
  - o No
  - o Don't know

F16. 15C

10. Do y	a take any medications for the purpose of treating memory loss such as dementia?
οÝ	
0 N	
11 Are	ou allergic to any medications?
0 3	•
O :	o Which Medication(s) [drop down menu]
0 1	

12. Are you taking any other medications including vitamins or herbal supplements such as Ginkgo Biloba?Yes

- YesWhich Medication(s) [drop down menu]No
- 13. Have you ever been enrolled in a research study for galantamine?YesNo
  - o Don't know
- 14. Have you taken an investigational drug in the past 30 days or are you taking one now?

  O No, I have not taken an investigational drug in the past 30 days
  - O Yes, I have taken an investigational drug in the past 30 days
  - o Yes, am taking an investigational drug now
- 15. How many drinks do you consume in a typical 24-hour period?
  - o 1-2 drinks
  - o 3-5 drinks
  - o 6-8 drinks
  - o more than 8 drinks
- 16. Have you/patient had a CT scan or MRI of the head during the last 12 months?

Yes No

F16.15D



## SCREEN #2: PATIENT NOT ELIGIBLE FOR STUDY

We appreciate your interest in this study. Unfortunately, from the information you have provided, you are not a candidate for participation in this study. May we have your permission to contact you in the future with information about this or other studies?

- o Yes, contact me.
- o No, I do not want to be contacted.

F16, 15E



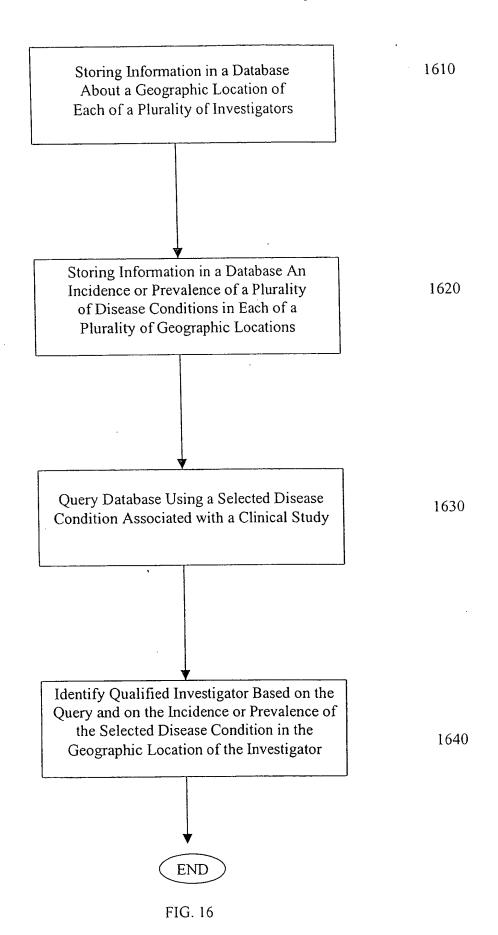
### SCREEN #3: PATIENT POTENTIALLY ELIGIBLE FOR STUDY:

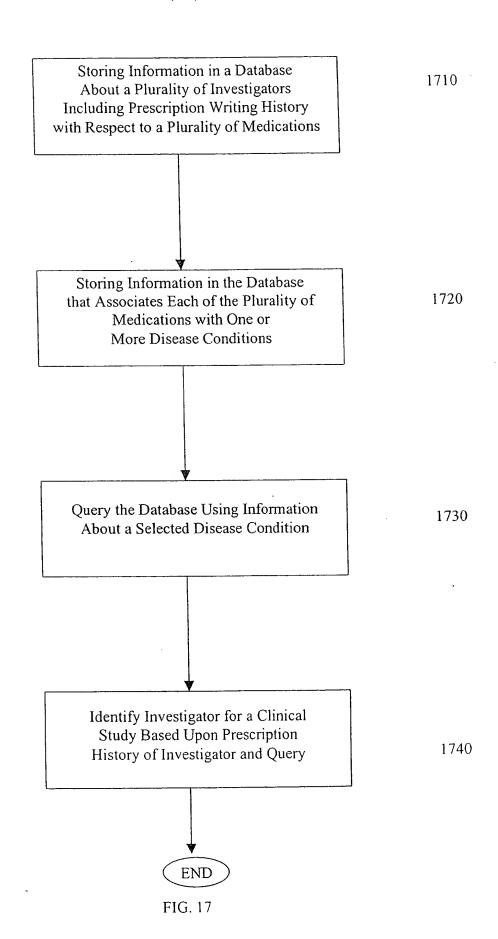
Based on your responses, you may be eligible for the clinical study. We will forward this information to the research site you selected. The research site will contact you shortly to ask you further questions about your health, and possibly to schedule an appointment for the first visit. In the meantime, we will send you a Welcome Kit that contains information about the study. If the site does not contact you within 5-7 business days, please feel free to call the number that will be included in your mailed materials.

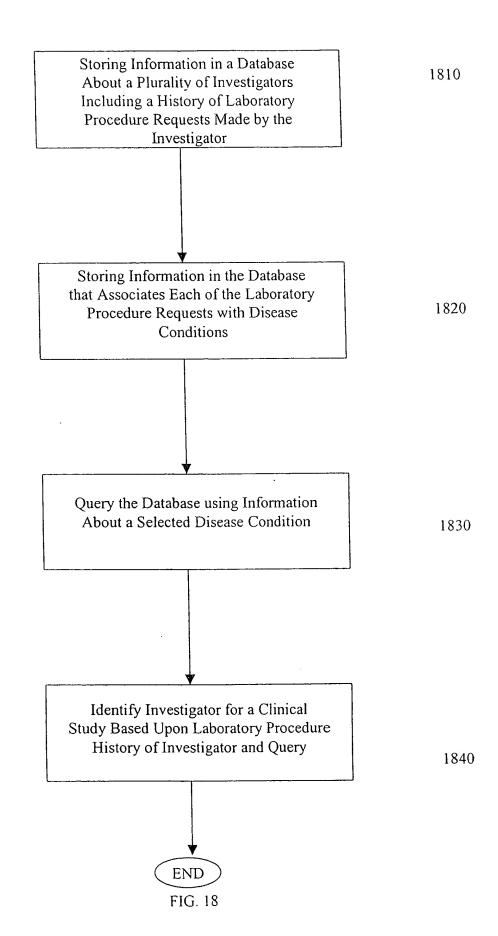
In the event that you do not participate in this particular study, may we have your permission to contact you in the future about other studies?

- o Yes, contact me
- o No, I do not want to be contacted

F16.15F







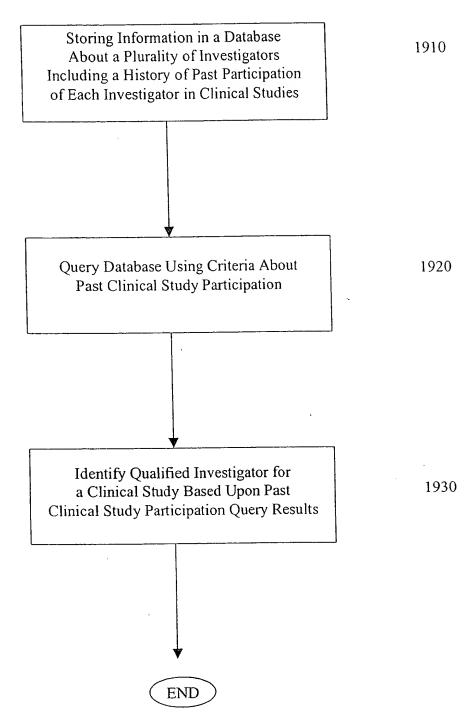
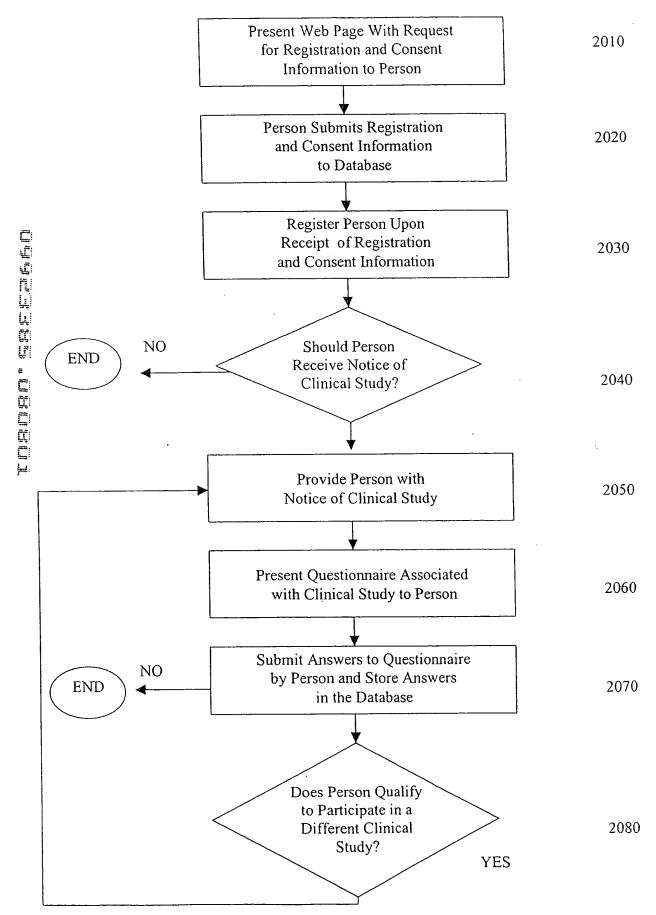
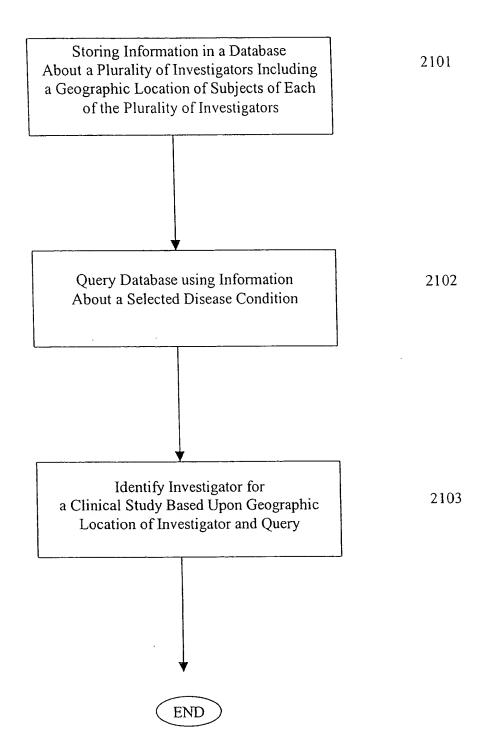


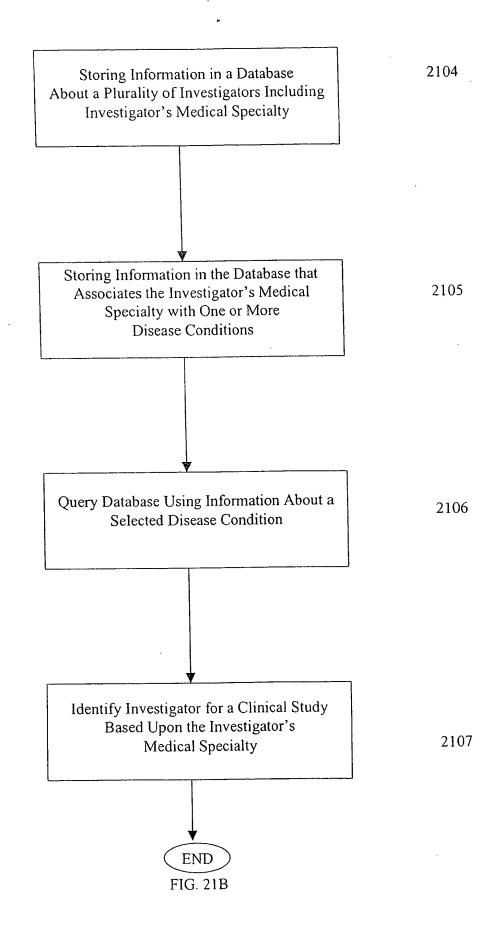
FIG. 20

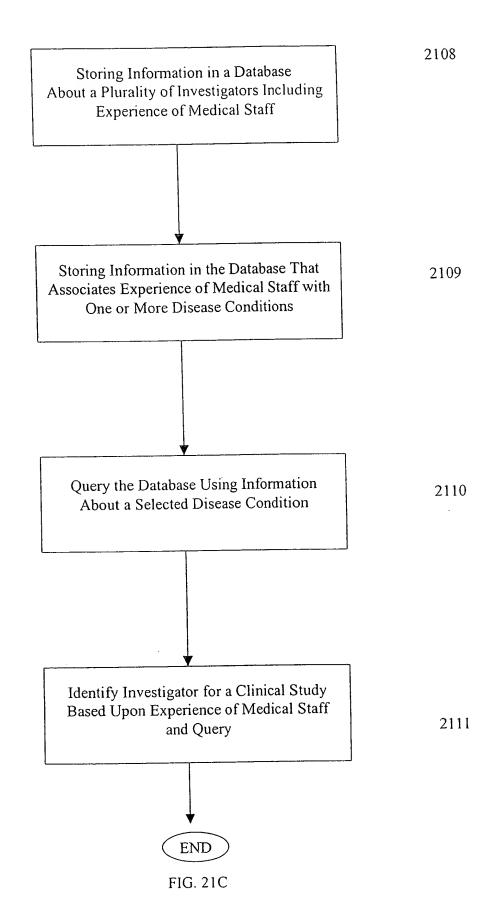












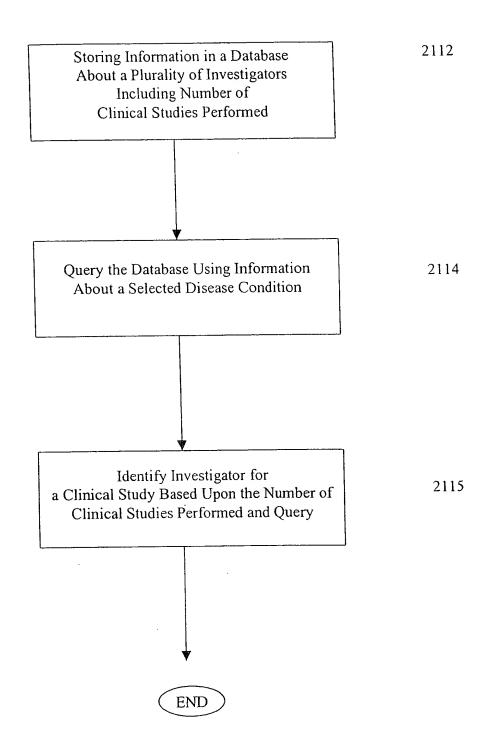
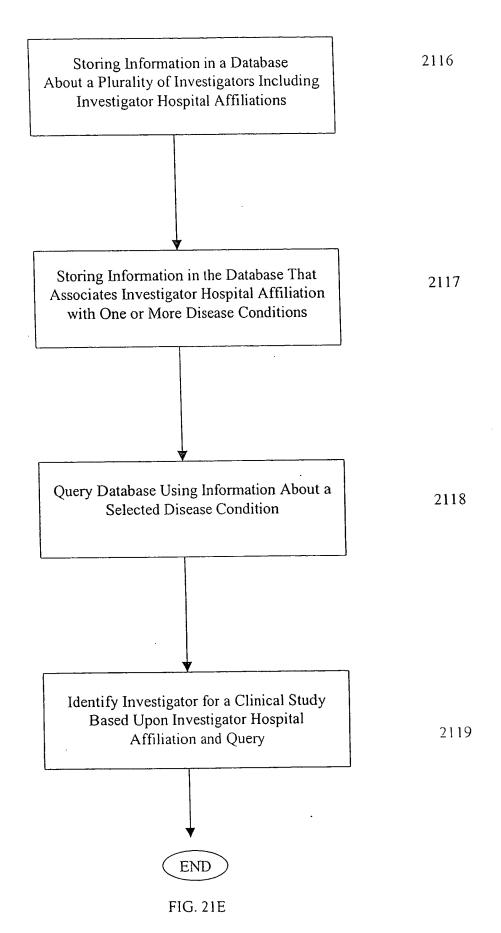


FIG. 21D



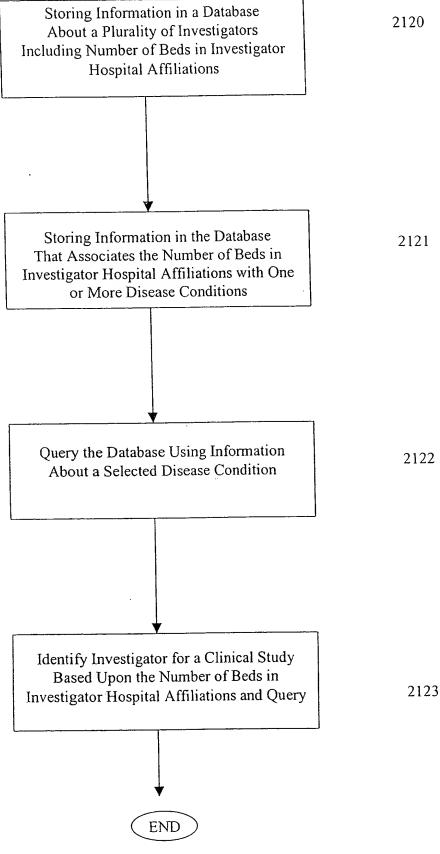


FIG. 21F



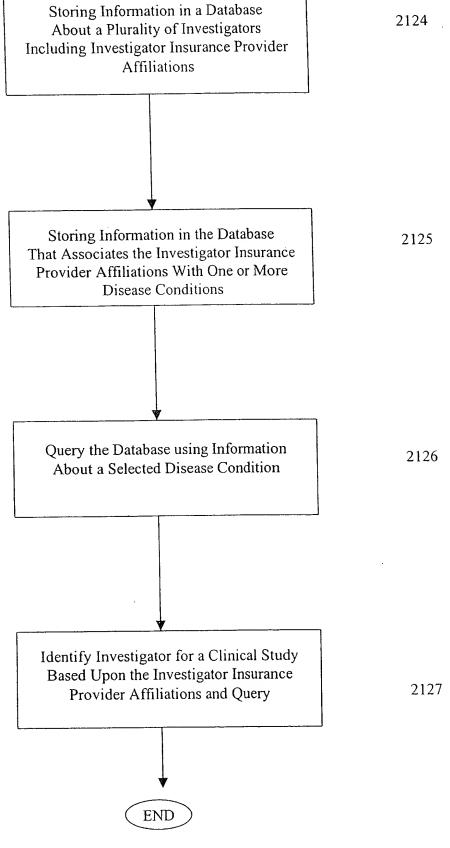


FIG. 21G -



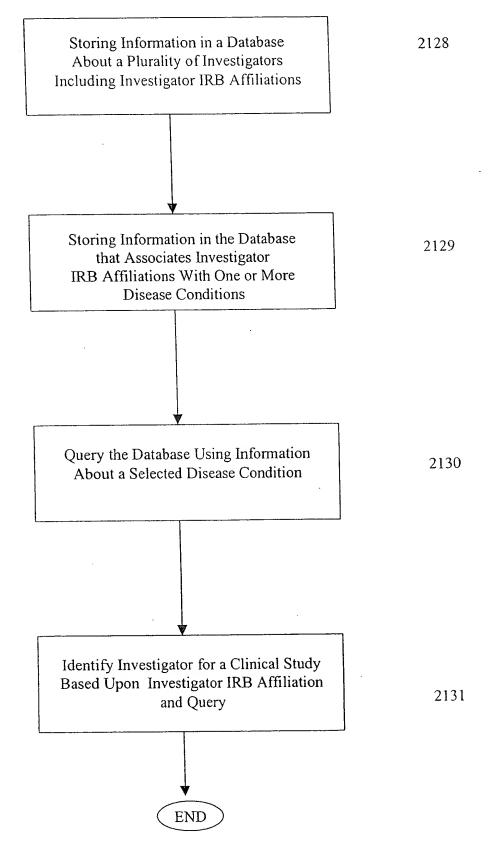
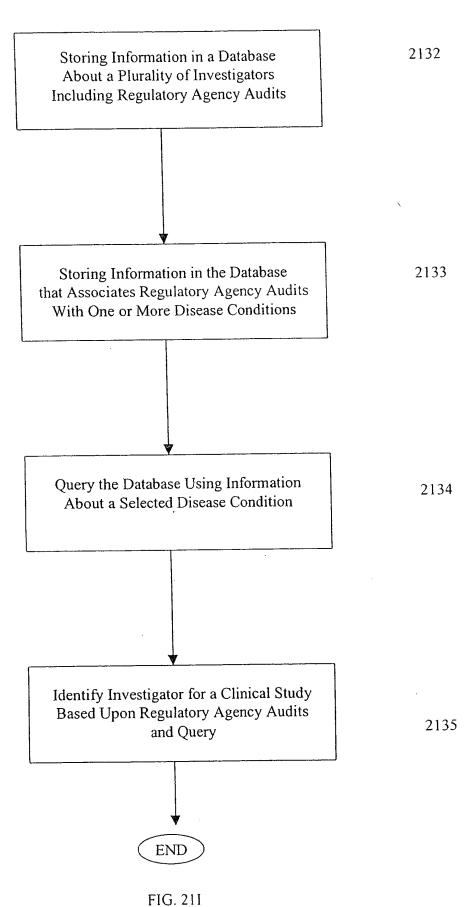
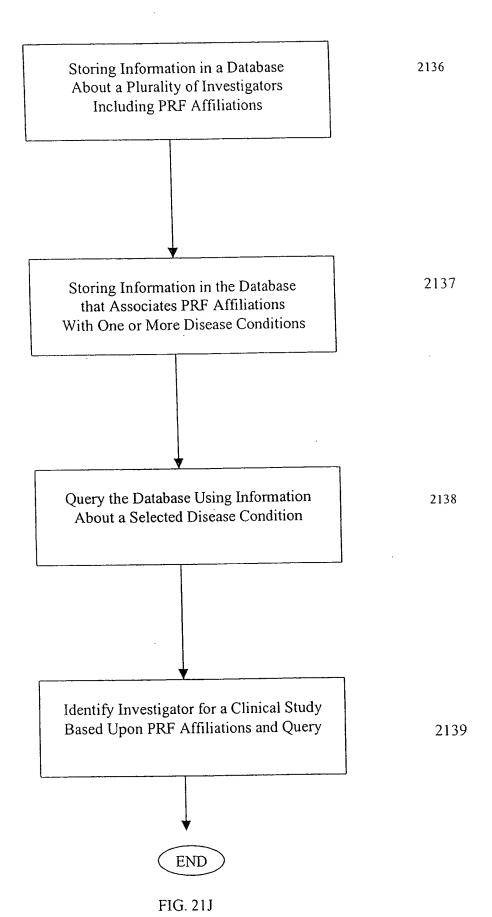
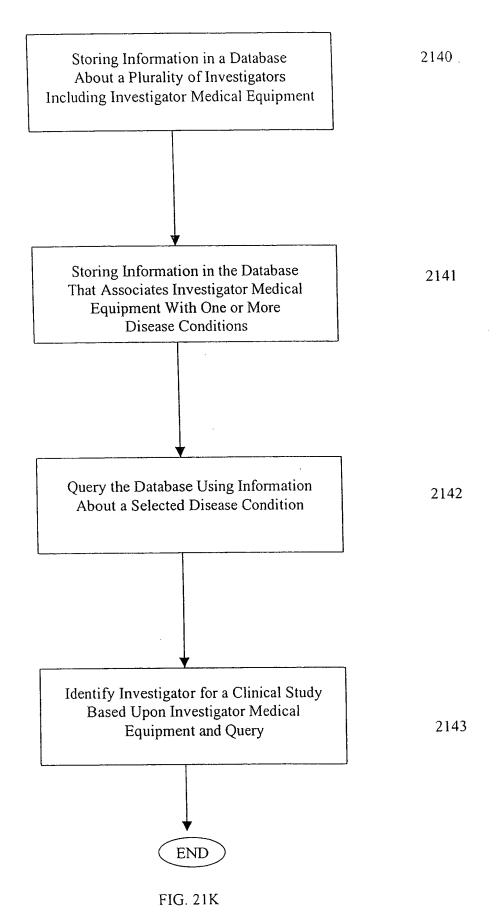


FIG. 21H

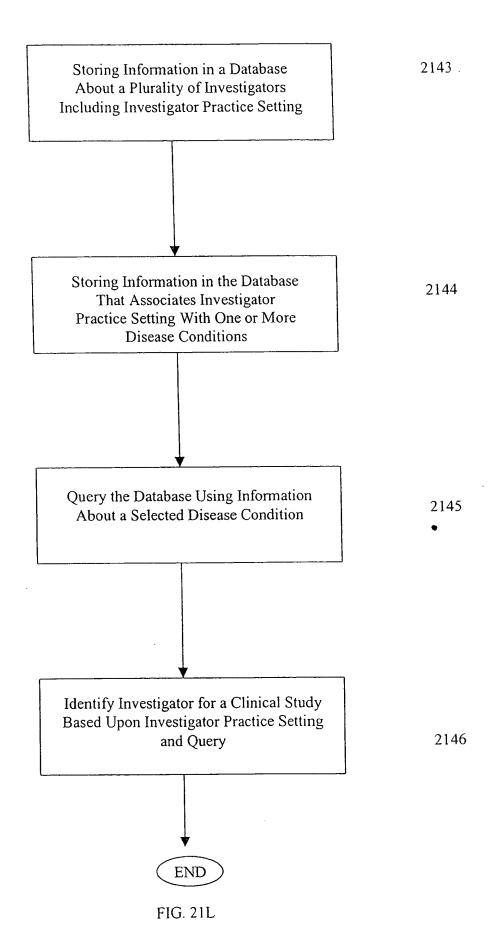


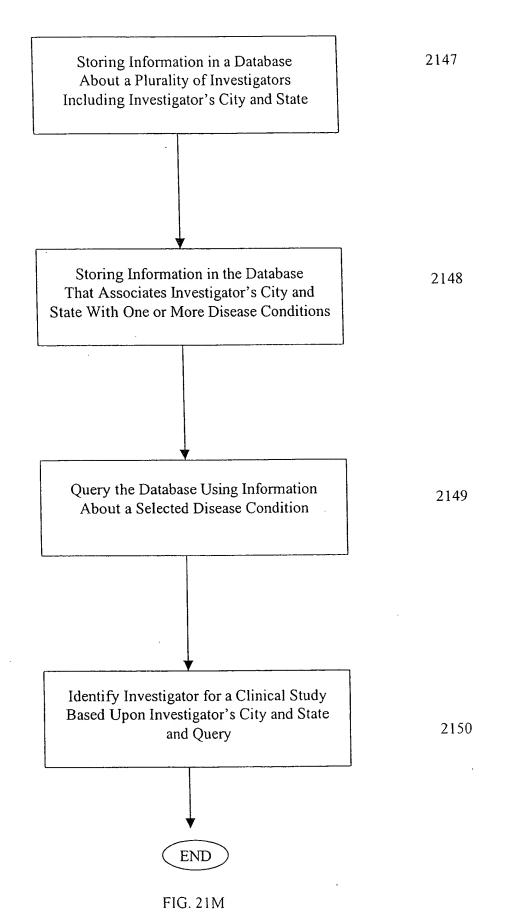


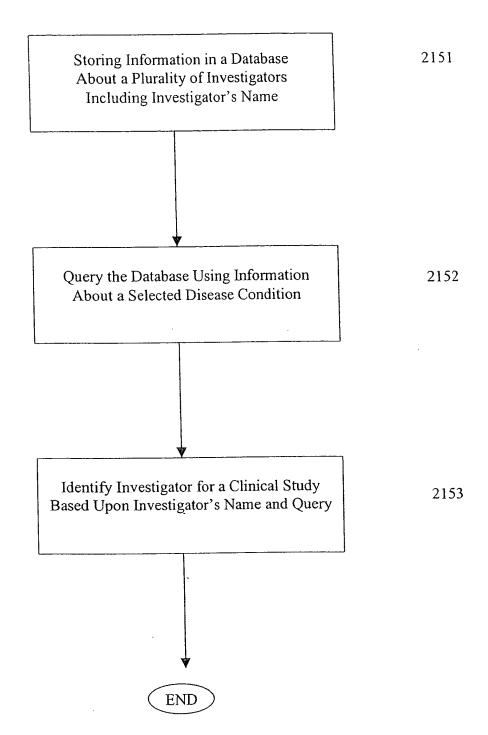












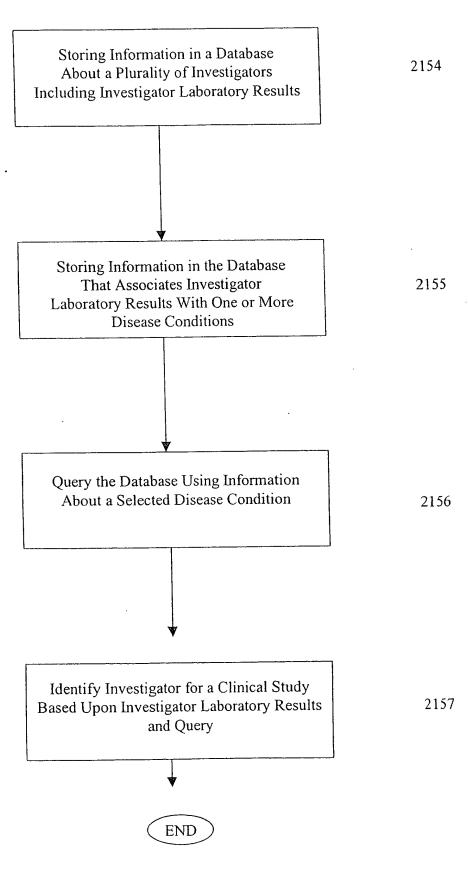


Fig. 210

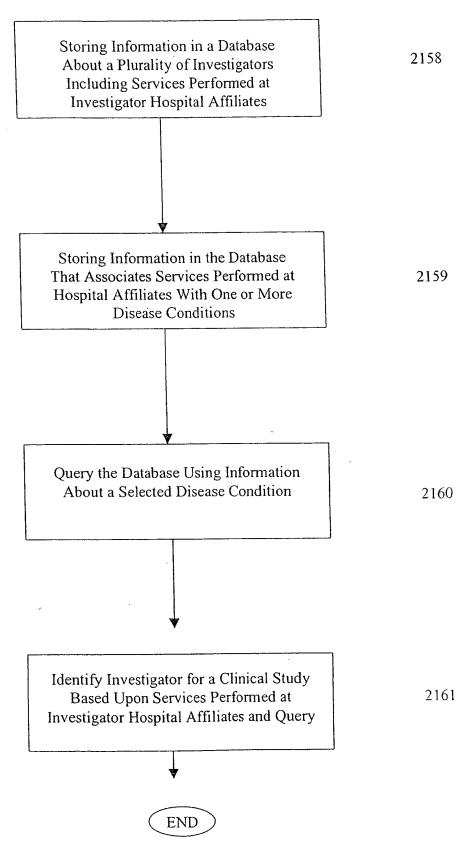


Fig. 21P

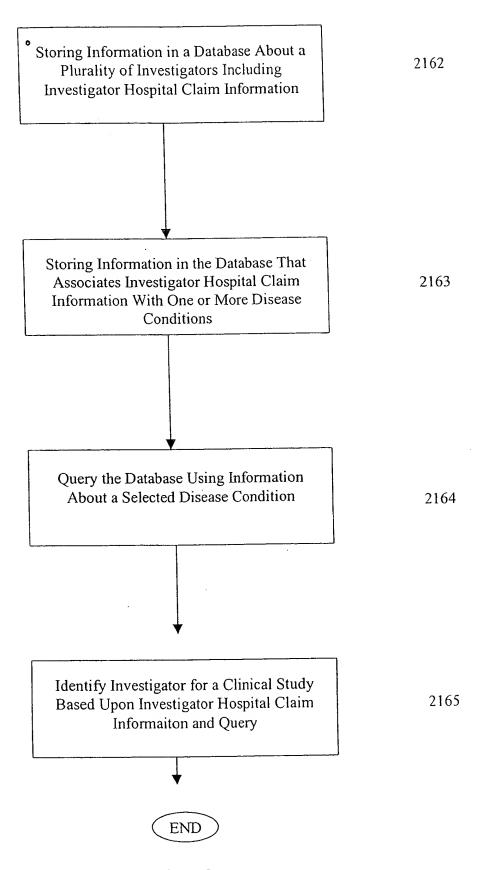
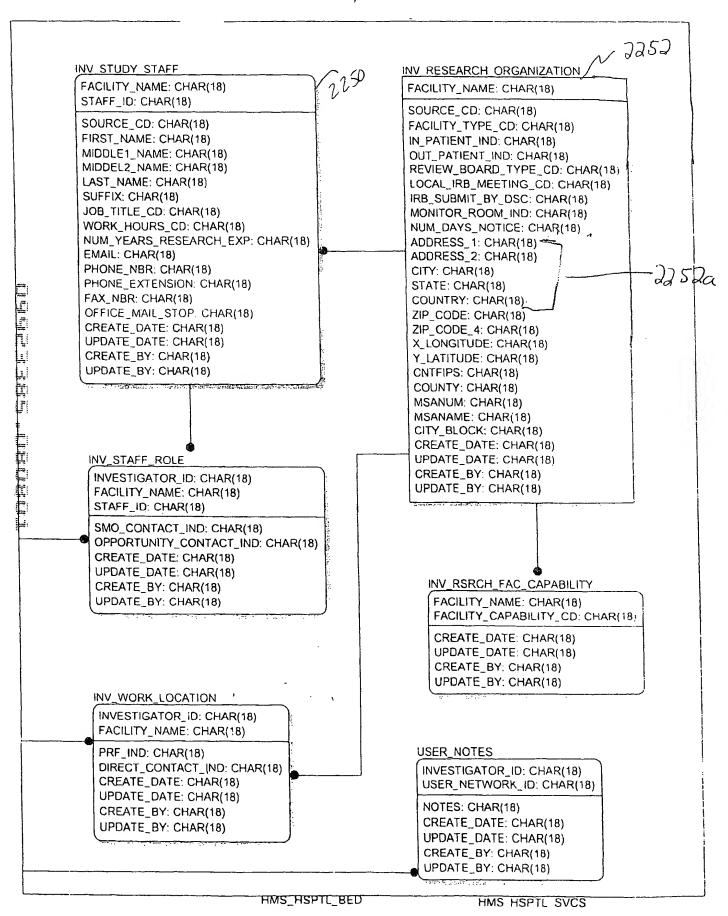


Fig. 21Q

-2220 2210 INV STUDY PERFORMANCE INVESTIGATOR ID: CHAR(18) STUDY PRF ID: CHAR(18) INV INVESTIGATOR SOURCE\_CD: CHAR(18) INVESTIGATOR\_ID: CHAR(18) SPONSOR\_ID: CHAR(18) SOURCE CD: CHAR(18) SPONSOR\_CRO\_NAME: CHAR(18) HMS\_ID: CHAR(18) PROTOCOL\_NUMBER: CHAR(18) FIRST\_NAME: CHAR(18) STUDY PHASE\_CD: CHAR(18) MIDDLE1: CHAR(18) DRUG\_NAME: CHAR(18) MIDDLE2: CHAR(18) DRUG CLASS: CHAR(18) LAST NAME: CHAR(18) THERA\_CONDITION\_CD: CHAR(18) SUFFIX: CHAR(18) START\_DATE: CHAR(18) COUNTRY: CHAR(18) NUM\_ENROLLMENT\_COMMITMENT: CHAR(18) SOC\_SEC\_NBR: CHAR(18) NUM\_PATIENTS\_ENROLLED: CHAR(18) IND UPIN: CHAR(18) ENROLLMENT\_MONTHS: CHAR(18) SEX: CHAR(18) ENROLLMENT\_MET\_IND: CHAR(18) DOB: CHAR(18) TIMEFRAME\_MET\_IND: CHAR(18) MED SCHOOL CD: CHAR(18) PLACEBO RESPONSE RATE: CHAR(18) GRADUATION\_YEAR: CHAR(18) NUM\_PATIENTS\_EVALUABLE: CHAR(18) RSDNCY\_ORG: CHAR(18) MICROBIOLOGIC\_EVALUABLE: CHAR(18) RSDNCY\_CITY: CHAR(18) BACTERIAL\_EVALUABLE: CHAR(18) FLLWSHP\_ORG: CHAR(18) NOTES: CHAR(18) FLLWSHP\_CITY: CHAR(18) CREATE\_DATE: CHAR(18) DEGREE1: CHAR(18) UPDATE\_DATE: CHAR(18) DEGREE2: CHAR(18) CREATE\_BY: CHAR(18) PHONE\_NBR: CHAR(18) UPDATE\_BY: CHAR(18) PHONE\_EXTENSION: CHAR(18) FAX\_NBR: CHAR(18) EMAIL: CHAR(18) 2230 INV\_SPECIALTY CREDENTIAL: CHAR(18) INVESTIGATOR ID: NUMBER(8) DELETE\_REASON\_CD: CHAR(18) SPECIALTY\_CD: VARCHAR2(6) DELETE\_REQUEST\_DATE. CHAR(18) WRONG\_NUMBER\_IND: CHAR(18) SOURCE CD: VARCHAR2(12) CV\_RECEIVED\_DATE: CHAR(18) BOARD COMPLETE CD: VARCHAR2(12) QUESTIONNAIRE\_RETURNED\_DATE: CHAR(18) CREATE DATE: DATE SMO RELATIONSHIP CD: CHAR(18) UPDATE\_DATE: DATE PRACTICE\_TYPE\_CD: CHAR(18) CREATE\_BY: INTEGER PRIMARY\_IN\_OUT\_CD: CHAR(18) UPDATE BY: INTEGER CRO\_NUM\_DAYS\_NOTICE: CHAR(18) \_ PHASE1\_EXPERIENCE\_IND: CHAR(18) 2240 PHASE2 EXPERIENCE IND: CHAR(18) INV\_PATIENT\_POPULATION PHASE3\_EXPERIENCE\_IND: CHAR(18) INVESTIGATOR ID: CHAR(18) PHASE4\_EXPERIENCE\_IND: CHAR(18) INDICATION\_CD: CHAR(18) PATIENT DATABASE\_IND: CHAR(18) SOFTWARE PACKAGE NAME: CHAR(18) ANNUAL\_PATIENTS\_TREATED: CHAR(18) CREATE\_DATE: CHAR(18) ANNUAL NEW\_PATIENTS\_TREATED; CHAR(18) UPDATE\_DATE: CHAR(18) INTERESTED IND: CHAR(18) CREATE\_BY: CHAR(18) CREATE\_BY: CHAR(18) UPDATE\_BY: CHAR(18) UPDATE\_BY: CHAR(18) CREATE DATE: CHAR(18) UPDATE\_DATE: CHAR(18)

224

HMS INVESTIGATOR



73/89

STLDEV01 -- Display1 / Investigator HMS\_INVESTIGATOR HMS\_HSPTL\_AFFLTN -2240 CONTACT\_ID: NUMBER(7) CONTACT ID: NUMBER(7) INVESTIGATOR ID: CHAR(18) HMS HOSP ID: VARCHAR2(9) INVESTIGATOR ID: CHAR(18) HMS ID: VARCHAR2(12) SOC SEC NBR: NUMBER(9) CREATION\_DATE: DATE IND UPIN: VARCHAR2(7) UPDATE\_DATE: DATE FIRST NAME: VARCHAR2(25) MIDDLE NAME 1: VARCHAR2(25) HMS\_SPECIALTY MIDDLE NAME 2: VARCHAR2(25) CONTACT\_ID: NUMBER(7) LAST\_NAME: VARCHAR2(50) SPECIALTY CD: VARCHAR2(8) SUFFIX: VARCHAR2(10) INVESTIGATOR ID: CHAR(18) CREDENTIAL: VARCHAR2(3) CREATION\_DATE: DATE SEX: VARCHAR2(1) UPDATE\_DATE: DATE DOB: NUMBER(10) H**MS≈DEA**wwererressezara MED SCHOOL CD: VARCHAR2(8) GRADUATION\_YEAR: VARCHAR2(4) CONTACT\_ID: NUMBER(7) RSDNCY\_ORG: VARCHAR2(100) DEA NBR: VARCHAR2(10) RSDNCY\_CITY: VARCHAR2(60) INVESTIGATOR\_ID: CHAR(18) FLLWSHP\_ORG: VARCHAR2(100) CREATION DATE: DATE FLLWSHP\_CITY: VARCHAR2(60) UPDATE\_DATE: DATE CREATION DATE: DATE HMS\_BOARD CERT UPDATE\_DATE: DATE CREDENTIAL\_2: VARCHAR2(3) CONTACT\_ID: NUMBER(7) INTRNSHP NAME: VARCHAR2(100) CERT\_CD: VARCHAR2(8) INTRNSHP\_CITY: VARCHAR2(60) INVESTIGATOR ID: CHAR(18) INTRNSHP\_STATE: VARCHAR2(2) CREATION\_DATE: DATE UPIN\_SANC: VARCHAR2(50) UPDATE\_DATE: DATE STATE\_SANC: VARCHAR2(50) RSDNCY\_STATE: VARCHAR2(2) HMS\_LANGUAGE FLLWSHP\_STATE: VARCHAR2(2) CONTACT\_ID: NUMBER(7) LANGUAGE\_CD: VARCHAR2(10) INVESTIGATOR\_ID: CHAR(18) HMS\_INV\_ADDRESS CONTACT ID: NUMBER(7) CREATION DATE: DATE ADDRESS\_ID: NUMBER(6) UPDATE\_DATE: DATE INVESTIGATOR\_ID: CHAR(18) HMS INSURANCE AFFLIN HMS\_ID: VARCHAR2(12) CONTACT ID: NUMBER(7) TIER: NUMBER(3) INSURANCE\_COMPANY CD: VARCHAR2(50) FIRM\_NAME: VARCHAR2(100) INVESTIGATOR ID: CHAR(18) ADDRESS\_1: VARCHAR2(75) CREATION DATE: DATE ADDRESS 2: VARCHAR2(75) UPDATE\_DATE: DATE PHONE NBR: NUMBER(15) HMS GRP UPIN FAX\_NBR: NUMBER(15) CITY: VARCHAR2(35) CONTACT\_ID: NUMBER(7) STATE: VARCHAR2(2) GRP UPIN: VARCHAR2(8) ZIP\_CODE: NUMBER(10) INVESTIGATOR ID: CHAR(18) ZIP\_CODE\_4: NUMBER(4) CREATION\_DATE: DATE X\_LONGITUDE: NUMBER(15) UPDATE\_DATE: DATE Y LATITUDE: NUMBER(15) HMS\_EMPLYR\_TAX\_TD MSANUM: NUMBER(12) MSANAME: VARCHAR2(45) CONTACT\_ID: NUMBER(7) COUNTY: VARCHAR2(30) EMPLR\_TAX\_ID: NUMBER(10) CNTFIPS: NUMBER(12) INVESTIGATOR ID: CHAR(18) CITY BLOCK: VARCHAR2(30) CREATION\_DATE: DATE CREATION\_DATE: DATE UPDATE\_DATE: DATE UPDATE\_DATE: DATE





STLDEV01 - Display1 / Investigator

REPIAB\_SVCS: VARCHAR2(1)
RESPIR\_SVCS: VARCHAR2(1)
SELFCARE\_SVCS: VARCHAR2(1)
SKNLT\_SVCS: VARCHAR2(1)
SOCSVC\_SVCS: VARCHAR2(1)
SPEECH\_SVCS: VARCHAR2(1)
THERD\_SVCS: VARCHAR2(1)
TRAUMA\_SVCS: VARCHAR2(1)
XRADT\_SVCS: VARCHAR2(1)
CREATION\_DATE: DATE
UPDATE\_DATE: DATE

which are and the management of the same

22)

STLDEV01 - Display1 / Investigator

CONTACT\_ID: NUMBER(7) HMS HOSP\_ID: VARCHAR2(9) INVESTIGATOR ID: CHAR(18)

HM2\_HSPIL\_BED

HMS STF BEDS: NUMBER(9) HMS\_HSP\_BEDS: NUMBER(9) HMS\_TOT\_BEDS: NUMBER(9) HMS\_STRM\_BEDS: NUMBER(9) HMS\_LTERM\_BEDS: NUMBER(9)

HMS\_MDSRG\_BEDS: NUMBER(9) HMS\_ICU\_BEDS: NUMBER(9)

BEDS OK: VARCHAR2(5) ICU BEDS: NUMBER(9)

CCU BEDS: NUMBER(9)

SICU\_BEDS: NUMBER(9) NICU\_BEDS: NUMBER(9)

NINT\_BEDS: NUMBER(9)

PICU BEDS: NUMBER(9)

PEDI\_BEDS: NUMBER(9)

OBGN BEDS: NUMBER(9) PSYC BEDS: NUMBER(9)

BURN\_BEDS: NUMBER(9) ALCH\_BEDS: NUMBER(9)

REHB\_BEDS: NUMBER(9)

OTHR\_BEDS: NUMBER(9)

CREATION\_DATE: DATE

UPDATE\_DATE: DATE

HMS HSPTL

CONTACT\_ID: NUMBER(7) HMS\_HOSP\_ID: VARCHAR2(9) INVESTIGATOR\_ID: CHAR(18)

HSPTL\_NAME: VARCHAR2(100) DEPT\_NAME: VARCHAR2(50) BRANCH\_NAME: VARCHAR2(50) ADDRESS\_1: VARCHAR2(75) ADDRESS\_2: VARCHAR2(75)

CITY: VARCHAR2(25) STATE: VARCHAR2(2)

ZIP\_CODE: VARCHAR2(6) 計ZIP\_CODE\_4: VARCHAR2(4)

PHONE\_NBR: VARCHAR2(13)

CEO: VARCHAR2(50) FIPS5: VARCHAR2(10)

COUNTY: VARCHAR2(50) MSANUM; VARCHAR2(12)

MSANAME: VARCHAR2(50) CENSUS\_ID: VARCHAR2(20)

X\_LONGITUDE: VARCHAR2(15)

Y\_LATITUDE: VARCHAR2(15)

SRVC\_CD: VARCHAR2(5) CTRL\_CD: VARCHAR2(5)

LOS\_CD: VARCHAR2(5)

UNV\_HSPTL\_IND: VARCHAR2(1) TCH\_HSPTL\_IND: VARCHAR2(1)

TEACHHOSP\_IND: VARCHAR2(1)

RESIDENCY\_IND: VARCHAR2(1)

MED\_SCHL\_IND: VARCHAR2(1)

ALLIED SCHL\_IND: VARCHAR2(1) JCAHO\_IND: VARCHAR2(1)

MEDICARE\_IND: VARCHAR2(1)

CANCERCTR\_IND: VARCHAR2(1) CLOSED\_IND: VARCHAR2(1)

CREATION\_DATE: DATE

UPDATE\_DATE: DATE

CONTACT\_ID: NUMBER(7) LICENSE\_STATE\_CD: VARCHAR2(2) INVESTIGATOR ID: CHAR(18)

LICENSE\_YEAR: NUMBER(4) CREATION\_DATE: DATE UPDATE\_DATE: DATE

HMS HSPIL\_SVCS

CONTACT\_ID: NUMBER(7) HMS\_HOSP\_ID: VARCHAR2(9)

INVESTIGATOR\_ID: CHAR(18) AIDS\_SVCS: VARCHAR2(1) ANSTH\_SVCS: VARCHAR2(1) ANGPLSTY\_SVCS: VARCHAR2(1) BLOODBNK\_SVCS: VARCHAR2(1) BMTRNSPL SVCS: VARCHAR2(1) BURNCTR\_SVCS: VARCHAR2(1) CRDCTH\_SVCS: VARCHAR2(1) CVSRGY\_SVCS: VARCHAR2(1) CHIRO\_SVCS: VARCHAR2(1) CLPSY\_SVCS: VARCHAR2(1) CT\_SVCS: VARCHAR2(1) DENTL\_SVCS: VARCHAR2(1) ULTRSND\_SVCS: VARCHAR2(1) DIETRTY\_SVCS: VARCHAR2(1) ECARD\_SVCS: VARCHAR2(1) ECONV\_SVCS: VARCHAR2(1) EMRGCY\_SVCS: VARCHAR2(1) ESWL\_SVCS: VARCHAR2(1) LABAN\_SVCS: VARCHAR2(1) HEART\_SVCS: VARCHAR2(1) HRTLUNG\_SVCS: VARCHAR2(1) HEMDIAL\_SVCS: VARCHAR2(1) HOMCRE SVCS. VARCHAR2(1) HOSPCE\_SVCS: VARCHAR2(1) CCU\_SVCS: VARCHAR2(1) ICU\_SVCS: VARCHAR2(1) KIDNEY\_SVCS: VARCHAR2(1) LABCLNC\_SVCS: VARCHAR2(1) . LIVER SVCS: VARCHAR2(1) LUNG\_SVCS: VARCHAR2(1) MEGVRAD SVCS. VARCHAR2(1) NEONUNT\_SVCS: VARCHAR2(1) NICU SVCS: VARCHAR2(1) MRI\_SVCS: VARCHAR2(1) NEURO\_SVCS: VARCHAR2(1) NSURG SVCS: VARCHAR2(1) NUCMED\_SVCS: VARCHAR2(1) OBSRVA\_SVCS: VARCHAR2(1) OBSTE SVCS: VARCHAR2(1) OCCTH\_SVCS: VARCHAR2(1)

OPNHT\_SVCS: VARCHAR2(1)

OPTOM\_SVCS: VARCHAR2(1)

ORGAN\_SVCS: VARCHAR2(1)

OUTPAT\_SVCS: VARCHAR2(1)

OUTSRG SVCS: VARCHAR2(1)

PANCR\_SVCS: VARCHAR2(1)

PEDIAT\_SVCS: VARCHAR2(1)

PHARM\_SVCS: VARCHAR2(1) PHYTH SVCS: VARCHAR2(1)

PSTOP SVCS: VARCHAR2(1)

PSYED\_SVCS: VARCHAR2(1)

PULMON\_SVCS: VARCHAR2(1) RADIM SVCS: VARCHAR2(1) RECTH\_SVCS: VARCHAR2(1)

ORGBANK\_SVCS: VARCHAR2(1)

HMS\_LICENSE

FDA\_1572\_STAT

CONTACT\_ID: NUMBER(8)
INVESTIGATOR\_ID: CHAR(18)

NUM\_TRIALS\_LAST5: INTEGER
NUM\_TRIALS\_LAST4: INTEGER
NUM\_TRIALS\_LAST3: INTEGER
NUM\_TRIALS\_LAST2: INTEGER
NUM\_TRIALS\_LAST1: INTEGER
TOTAL\_TRIALS\_LIFETIME: INTEGER
FIRST\_YEAR: INTEGER
LAST\_YEAR: INTEGER

FDA\_1572

UPDATE\_DATE: DATE

CONTACT\_ID: NUMBER(7) FDA\_1572\_ID: NUMBER(7) INVESTIGATOR\_ID: CHAR(18)

HMS\_ID: VARCHAR2(12)

LAST\_NAME: VARCHAR2(100)
FIRST\_NAME: VARCHAR2(25)
MIDDLE\_INITIAL: VARCHAR2(1)
SUFX: VARCHAR2(5)
CRED1: VARCHAR2(8)
ORGNAME: VARCHAR2(100)
ADDRESS: VARCHAR2(100)
CITY: VARCHAR2(35)
STATE: VARCHAR2(2)
ZIP\_CODE: VARCHAR2(14)
COUNTRY: VARCHAR2(60)
YEAR: NUMBER(4)
RECEIPT\_DATE: DATE

RECEIPT\_YEAR: NUMBER(4)
ORG\_TYPE: VARCHAR2(3)
CREATION\_DATE: DATE

FDA\_483

CONTACT\_ID: NUMBER(7)
FDA\_DFCNCY\_ID: NUMBER(8)
CONTACT\_ID: NUMBER(7)
INVESTIGATOR\_ID: CHAR(18)

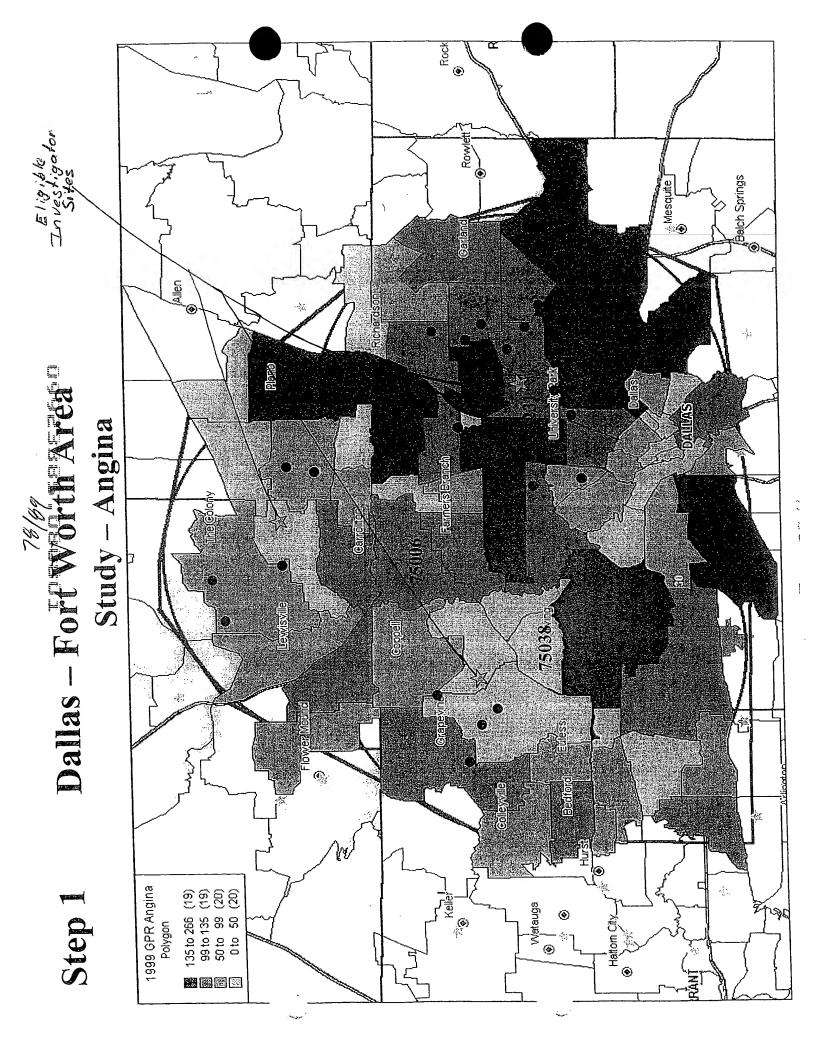
HMS\_ID: VARCHAR2(12)
LAST\_NAME: VARCHAR2(100)
FIRST\_NAME: VARCHAR2(25)
ORG: VARCHAR2(100)
ADDRESS: VARCHAR2(100)
CITY: VARCHAR2(35)
STATE: VARCHAR2(2)
ZIP\_CODE: VARCHAR2(14)
COUNTRY: VARCHAR2(60)
INSPCTN\_DATE: DATE
CLSSFCTN\_TYP: VARCHAR2(2)
CLSSFCTN\_CD: VARCHAR2(5)
DFCNCY\_CD: NUMBER(2)
CREATION\_DATE: DATE

SOF

Disease Incidence Searchan 딕 Z Study - Angina **○ ≥** ΔR 것 ス <u>س</u> 2 2 200 El Paso 0 Z 凇 **AZ** Phoenix F 2 Step WA

ソロロ

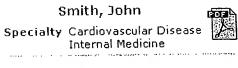
Ĺ



Rock Rowlett Balch Springs Case Study - Angina Step 2 Investigator Recruitment / Screening 135 to 266 (19) 99 to 135 (19) 50 to 99 (20) 0 to 50 (20) 1999 GPR Angina Polygon /√etauga









Contact Information	Primary Research Facility	Study Staff	Trial Experience	Provider	Hospital	Rrismatic Viev
					And the second s	The state of the s

Yellow = ABC Pharma Trial

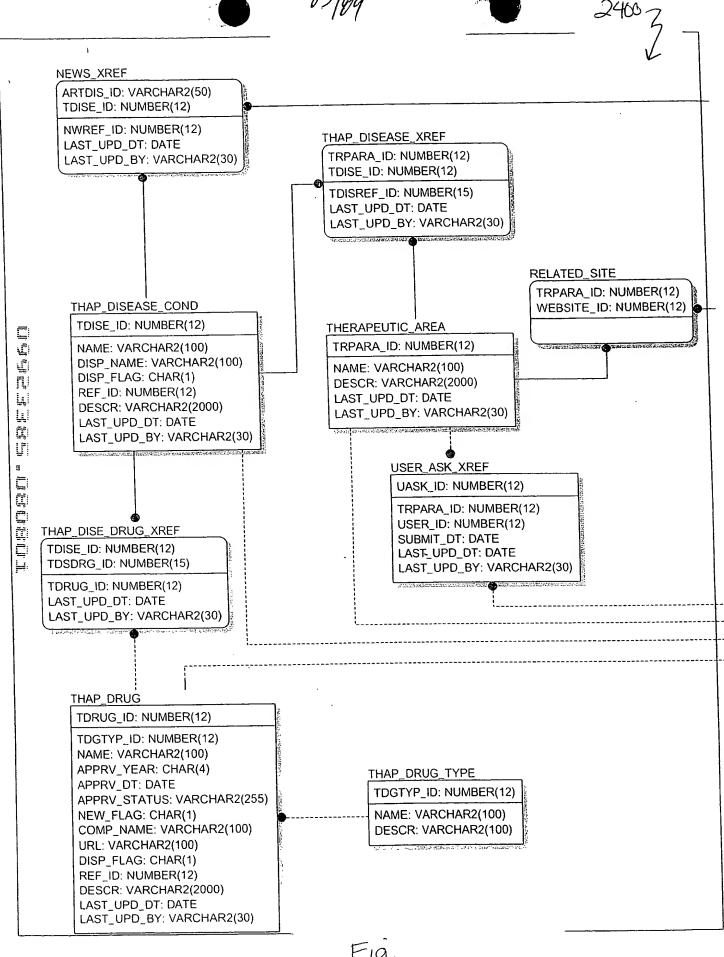
COSESSES SEES

Indication	Start Date	Enrollment Commitment	Evaluable Patients	Timeframe (months)	Enrollment Percentage	ABC Pharma Rank
APT	1/15/2001	12	8	12	70%	4
CHF	11/1/2000	10	9	9	90%	
CHF	10/5/2000	10	9	9 /	90%	
CHD	7/1/2000	8	3	6	40%	2
CAD	6/1/1999	15	12	6	80%	
CHT	2/15/1999	8	7	10/	90%	4 \
CHF	3/1/1998	10	8	/12	80%	3.\
CHD	3/22/1997	6	4	10	60%	
CHD	6/1/1996	8	6	10	80%	

(2302)

Data supplied by sponsor viewing 5creen (2304)

Fig. 23



F19.



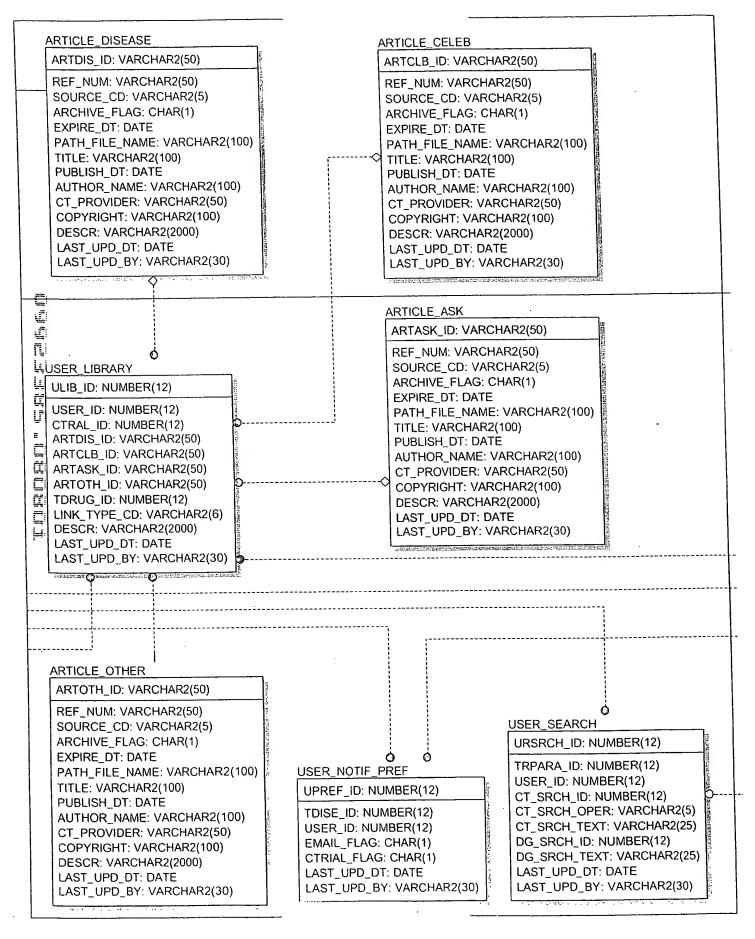
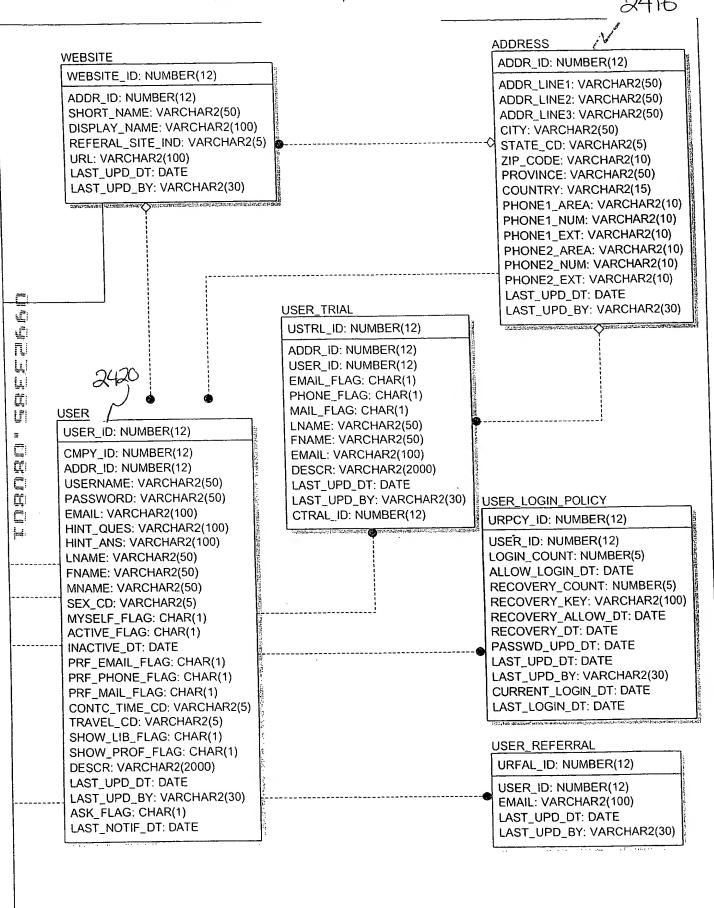


Fig. 24B



F19. 24C





CONTYP\_ID: NUMBER(12) NAME: VARCHAR2(100) DESCR: VARCHAR2(100)

## ACURIAN\_NOTIFICATION

NOTIF\_ID: NUMBER(12)

NOTIF\_TYPE: VARCHAR2(100) NOTIF\_DESC: VARCHAR2(100) LAST\_NOTIF\_DT: DATE

et alle de la commentation de la proposition de la commentation de la commentation de la commentation de la co

ACURIAN\_PUBLISH

PUBLISH\_ID: NUMBER(12) CONTYP\_ID: NUMBER(12) PUBLISH\_DATE: DATE TRPARA\_ID: NUMBER(12)

Fig. 24D

LOWLAND, CHURCH

ACULN\_COMPANY

COMPANY\_ID: NUMBER(8)

DESCRIPTION: VARCHAR2(132) COMPANY\_NAME: VARCHAR2(32)

TYPE\_CD: VARCHAR2(6)

K 2560

ACR MRGD TRIAL LISTING

SOURCE\_CD: VARCHAR2(6)
TRIAL\_LISTING\_ID: VARCHAR2(30)

SPONSOR COMPANY\_ID: NUMBER(8)

HEADER\_TXT: VARCHAR2(200)

DETAIL\_TXT: BLOB(4000)

DETAIL\_TXT\_URL: VARCHAR2(200) SORT\_PRIORITY\_CD: VARCHAR2(6)

DISPLAY\_IND: VARCHAR2(1)

DISPLAY\_START\_DATE: DATE DISPLAY\_END\_DATE: DATE

CREATE\_DATE: DATE

UPDATE\_DATE: DATE

ACR\_MRGD\_TRIAL\_INDICATION SOURCE\_CD: VARCHAR2(6)

TRIAL\_LISTING\_ID: VARCHAR2(30)

THERAPEUTIC\_AREA\_CD: VARCHAR2(6)

INDICATION\_CD: VARCHAR2(6)

ACR\_MRGD\_TRIAL\_SITE

SOURCE CD: VARCHAR2(6)

TRIAL\_LISTING\_ID: VARCHAR2(30)

TRIAL\_SITE\_ID: NUMBER(8)

SITE\_TXT: VARCHAR2(800)

SITE\_TXT\_URL: VARCHAR2(200)

STREET1: VARCHAR2(100)

STREET2: VARCHAR2(100)

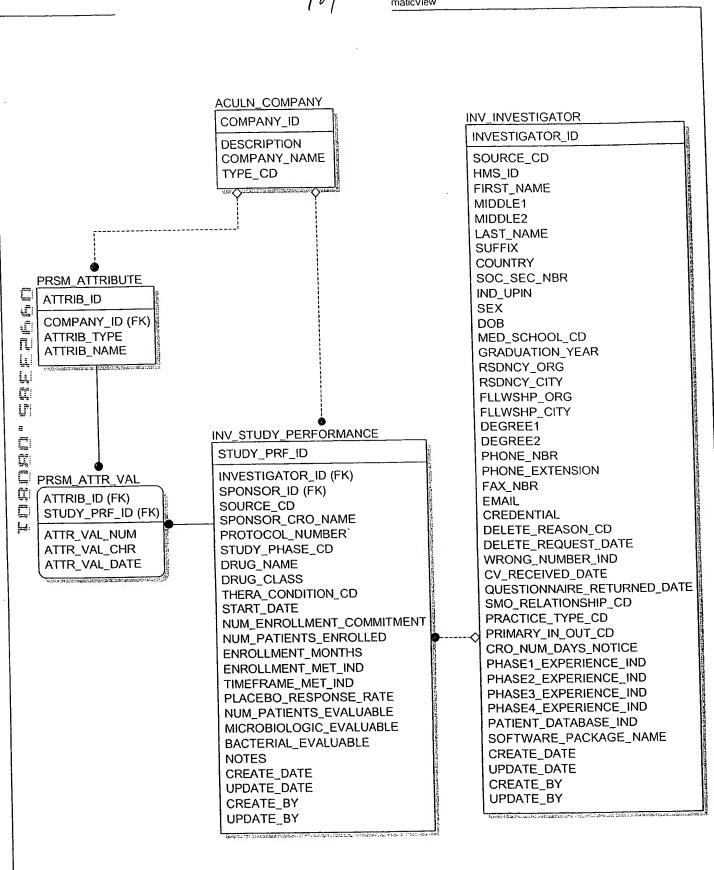
CITY: VARCHAR2(30)

STATE: VARCHAR2(2)

ZIP: NUMBER(5)

ZIP4: NUMBER(4)

F19.25



1, 1 / 1, 1 - 9:45:14 AM , 1/29/01

Fig. 26



89/89



